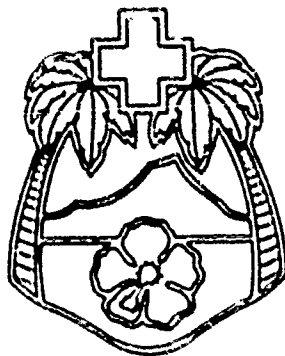


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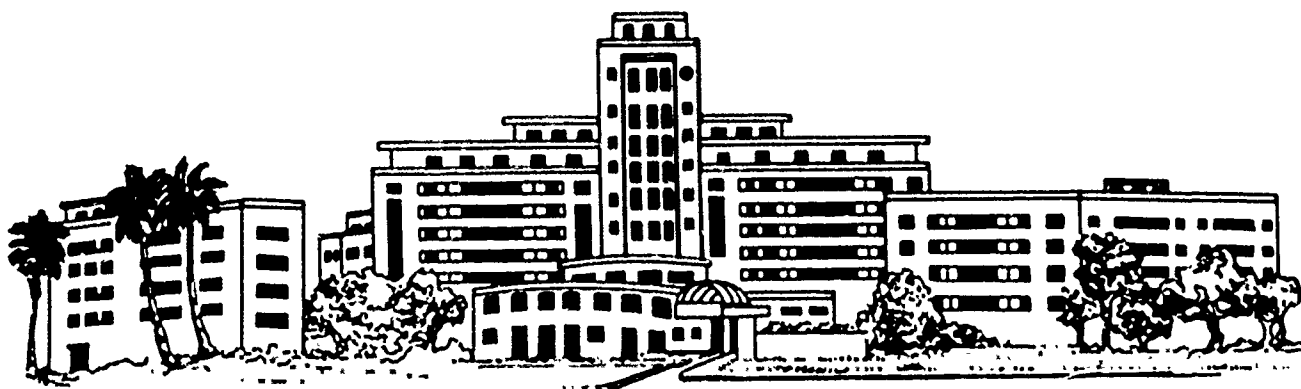
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## CLINICAL INVESTIGATION PROGRAM

REPORTS CONTROL SYMBOL MED-300 (R1)

**FISCAL YEAR 1989**

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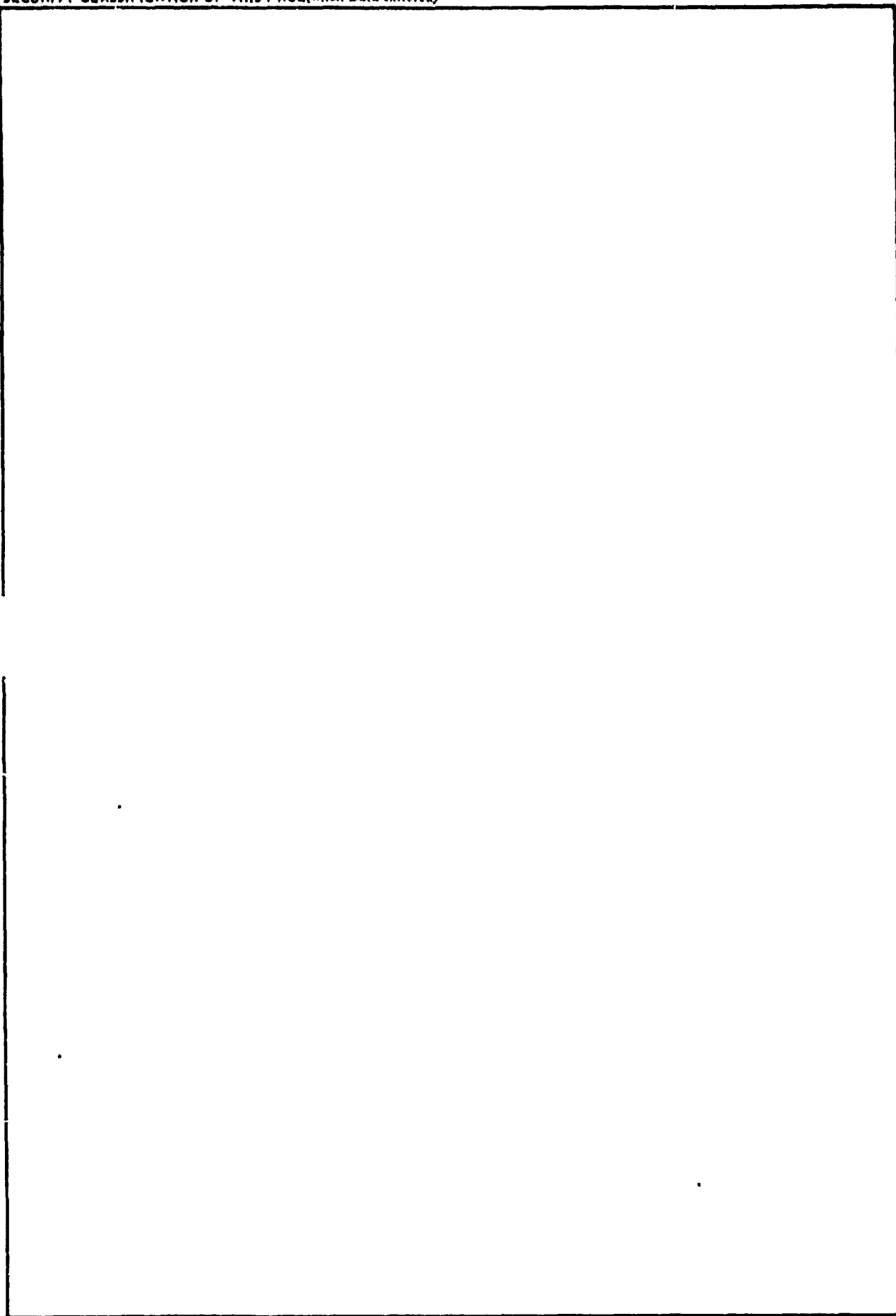
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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Clinical investigation; experimental projects; research projects; in-house research; publications, presentations of research data; project status; experimental design		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies those individuals who are conducting investigative protocols at Tripler Army Medical Center. An abstract of each project giving abbreviated technical objectives, methods, and progress is presented.		

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# ANNUAL PROGRESS REPORT

DEPARTMENT OF CLINICAL INVESTIGATION  
Reports Control Symbol MED-300(R-1)

FISCAL YEAR 1989  
1 October 1989



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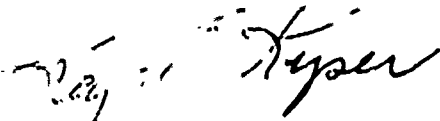
DEPARTMENT OF CLINICAL INVESTIGATION  
TRIPLER ARMY MEDICAL CENTER  
Tripler AMC, Hawaii 96859-5000



## FOREWORD

Building on the changes of last FY, investigators expanded research excitement at Tripler. An increasing number of clinical programs have started formal research training schedules, including research block time, insuring support and guidance by the teaching staffs to new investigators. Increasingly, physicians from within the clinical specialties sought collaboration with Dr. Claybaugh and our affiliated university researchers to insure that studies took advantage of next generation technology and nationally credible co-investigators. Excellent Tripler Command support, including midyear plus ups, made it possible to match resources to rapidly increasing research requirements. The joint Tripler-Kapiolani neonatology fellowship showed ever increasing growth of momentum in research with clinical payoffs of approval of increased number of fellows. Investigators in the fellowship program, in collaboration with University of Hawaii researchers, were awarded a privately funded multiyear program project grant, reflecting outside professional recognition of the national credibility of the program. The historic Tripler commitment to research in surgery is being rewarded by substantial increases in the quality and volume of research in Surgery. This has also been a record year for clinical research in OB-GYN with the number of papers accepted at the national meetings outstripping all other MEDCENs. Physicians in Psychiatry and Surgery had papers selected for awards at national meetings. CPT Beau Freund of our department was named the outstanding Army Allied Scientist. Dr. John Claybaugh was promoted to GM 15. His research area received recognition as well as additional funding from the US Army Medical Research and Development Command.

Matching the success of this year will be our greatest challenge next year.

  
KAY A. KYSER  
COL, MC  
Chief, Dept of Clinical Investigation

## ACKNOWLEDGEMENTS

I would like to take this opportunity to thank Mrs. Sharon M. Abe, Editorial Assistant, for the compilation, preparation and editing of this publication and Mrs. Candace M. Lord, Clerk-Typist, for her typing support.

DEPARTMENT OF CLINICAL INVESTIGATION  
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: To sponsor clinical investigation, in compliance with applicable laws, regulations and policies, to increase the academic professional stature of the MEDCEN.

B. TECHNICAL APPROACH: 1) Renew research documentation and advise the Commander and his institutional committees on matters pertaining to clinical investigation, and 2) Provide consultative and collaborative support to approved investigations.

C. STAFFING:

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Kyser, Kay A.	COL	61F9B	Chief
McCu'llen, Albert H.	MAJ	64C9B	Chief, Veterinary Service
Freund, Beau J.	CPT	68J00	Research Physiologist
Otto, Christopher L.	SSG	92B30	NCOIC
Conceicao, Mary Lou	SSG	92B3HM4	Former NCOIC(departed 10/89)
Brady, Anne V.	SSG	01H30	Biological Science Asst
Rawitz, Eileen C.	SSG	91T30	Animal Care Specialist
Anderson, Sandra J.	SGT	91T20	Animal Care Specialist
Johnson, Elsa L.	SPC	92B10	Medical Laboratory Specialist
Claybaugh, John R.	GM14	00413	Chief, Physiology Service
Sato, Aileen K.	GS11	00644	Medical Technologist
Ichimura, Wayne M.	GS11	00802	Biomedical Engineer
Hashiro, Glenn M.	GS09	00404	Biological Laboratory Tech
Abe, Sharon M.	GS07	01087	Editorial Assistant
Leighnor, Agatna M.	GS05	00318	Secretary (Typing)
Yee, Denise M. L.	WG04	03566	Animal Caretaker
Kullama, Linda K.***			Post Doctoral Fellow
Dice, Margaret S.**			Biological Laboratory Tech
Eichinger, Mark R.*			Biological Laboratory Tech
Griffith, Robert B.*			Biological Laboratory Tech
Hebden, Anthony****			Post Doctoral Fellow

\*MRDC Grant (Educational Contract)

\*\*Buffalo Grant (Educational Contract)

\*\*\*Leahi Grant (Kapiolani Hospital)

\*\*\*\*VA/DOD (Educational Contract)

Officers: 3 authorized; 4 required; 3 assigned.

Civilians: 6 authorized; 9 required; 9 assigned.

Enlisted: 6 authorized; 7 required; 6 assigned.

The number of personnel funded by grants and not included in the TDA: 8

D. FUNDING:

Funding Type	1989	SUNY Grant	VA Support Agreement	USMRDC Grant
Civilian personnel including benefits	\$318,681	\$ 313		
Consumable supplies	147,798	10,146	22,974	
Civilian contracts including consultants	10,268	3,180	8,115	\$3,400
TDY	24,890	1,096	1,268	
Noninvestment equipment (Minor MEDCASE)	28,276			
OMA Total	529,913			
MEDCASE	113,979			
Military	393,778			
TOTAL	\$1,037,670	\$14,735	\$32,357	\$3,400

E. PROGRESS: There is a continued reversal of a decade of decline. Issues of logistic support, space, people, and policy are all being addressed with solutions programmed over the next two years.

Number of residency and fellowship training programs that use Clinical Investigation: 14

37 Residents held approved protocols in 1989 with the total number of 47 protocols held by this group in 1989.

4 Fellows held approved protocols in 1989 with the total number of 4 protocols held by this group in 1989.

60 Hospital staff members held approved protocols in 1989 with the total number of 173 protocols held by this group in 1989.

F. PROBLEMS: See progress.

# HISTORY OF TAMC PROTOCOLS PRESENTATIONS, AND PUBLICATIONS

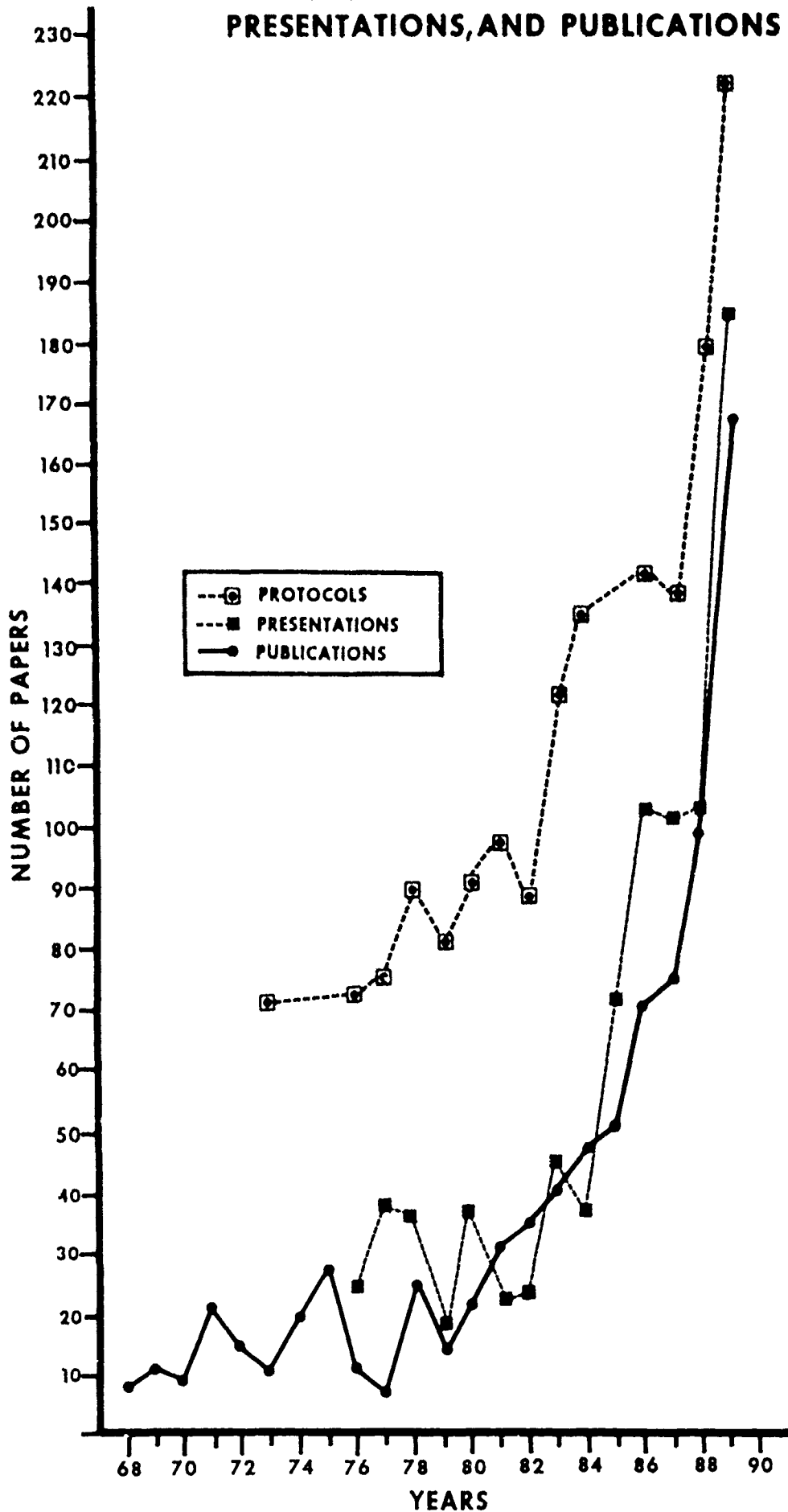


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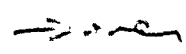
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## PRESENTATIONS - FY89

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#### USA DENTAC HAWAII

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#### DEPARTMENT OF MEDICINE

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Kopelman JN, Miyazawa K: Multifetal Pregnancies: The Tripler Experience. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Kopelman JN, Miyazawa K: Topical 5 Fluorouracil Treatment in Early Pregnancy: A Report of Two Cases. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Kopelman JN, Walton D, Wilson J, Miyazawa K: Antepartum Diagnosis of Arthrogyriposis Associated with Trisomy 18. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Kopelman JN, Wilson J, Miyazawa K: Hepatosplenic Schistosomiasis in Pregnancy: Report of a Case and Review of the Literature. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Letterie GS, Vause N, Miyazawa K: Mullerian Tract Abnormalities and Associated Auditory Deficiencies. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Letterie GS, Andrews SJ, Miyazawa K: Serial Monitoring of Serum Human Chorionic Gonadotropin (hCG) in Ectopic Pregnancies (EP) and First Trimester Spontaneous Abortions (AB). Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 6-10 November 1989

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Letterie GS, Laberge J, Miyazawa K: Fluoroscopically-guided Transcervical Canalization for Proximal Tubal Obstruction. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 1989

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Mandel RI, Burner JP, Miyazawa K: Endocardial Fibroelastosis: An Unusual Cause of Pulmonary Hypertension in Pregnancy. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 1989

Markenson GR, Hibbert ML, Kopelman JN, Miyazawa K: Unilateral Tubal Twin Gestation. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Markenson GR, Kopelman JN, Freund BJ, Claybaugh JR, Yamamoto PH, Miyazawa K: A Prospective Longitudinal Evaluation of Plasma Levels of Atrial Natriuretic Factor, Plasma Renin Activity, and Aldosterone, in patients at risk for Preeclampsia - a preliminary report. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 1989

McNulty K, Miyazawa K: Urological Injuries Encountered During Abdominal and Vaginal Hysterectomy. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 89

Miyazawa K, Vogel EJ, Bruner JP: Prenatal Diagnosis of Nevroid Basal Cell Carcinoma Syndrome: A Case Report. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 89

Mcorman AJ, Bruner JP, Miyazawa K: Fetal Supraventricular Tachycardia Successfully Treated with Maternal Digitalization. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 89

Ramirez EJ, Hernandez E, Miyazawa K: Cervical Conization Findings in Women with Dysplastic Cervical Cytology and Normal Colposcopy. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Rose S, Letterie GS, Miyazawa K: Pregnancy Rates Using Oil-Based and Water-Based Contrast Medium in the Evaluation of Tubal Patency. ACOG Armed Forces District Meeting, San Antonio, Texas, 6-10 November 1988

Shen-Gunther J, Andrews SJ, Miyazawa K: Primary Peritoneal Carcinomatosis: Report of Two Cases and Review of the Literature. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 89

Shen-Gunther J, Kopelman JN, Miyazawa K: Amniocentesis Quantified of Amnionic Fluid Index Assessments: Preliminary Findings. Armed Forces ACOG (AFACOG), Washington D.C., 5-9 November 89

Shen-Gunther J, Miyazawa K: Epidemiological Observation and Pathological Findings of Cervical Conization: The Tripler Experience. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 89

Thomas TL, Hibbert ML, Miyazawa K: Successful Full Term Pregnancy After Removal of all Ovarian Tissue in the First Trimester: A Case Report and Literature Review. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 89

Vogel E, Shen-Gunther J, Hibbert M, Miyazawa K: Ovarian Pregnancy in a Copper T IUD User. Armed Forces ACOG (AFACOG) Mtg, Washington D.C., 5-9 November 89

#### DEPARTMENT OF PATHOLOGY AND AREA LABORATORY SERVICES

Posey DM, Kark JA, Peterson BL, Robinowitz M, Coffey SE, Darcy TP, Virmani R: Causes of Sudden Unexpected Death During Military Basic Training. Am Fed for Clin Research, Washington D.C., April-May 1989

Seal LA, Lerud KS, Plymyer MR, Nadala C, Sprague MS: An Investigation of Hepatitis A Virus Infected Blood Products. Soc of Armed Forces Med Lab Scientists Meeting, San Antonio, Texas, March 1989

## DEPARTMENT OF PEDIATRICS

Alexander ME, Lovett EJ, Person DA: Postural Demonstration of Cross-sectional and M-mode Echocardiographic Mitral Valve Prolapse in Pediatric Patients with Clinical Mitral Valve Prolapse. Uniformed Services Pediatric Seminar, Honolulu, Hawaii, March 1989

Bass JW: Occult Bacteremia in Children - What to do about it. Guest Faculty, Annual Uniformed Service Pediatric Seminar. Princess Hotel, San Diego, California, 13-17 March 1988

Bass JW: Pertussis: Past, Present and Future, Kawasaki Syndrome and Look-a-Like Diseases. Annual Brooksaler Visiting Professor Lecturer, Department of Pediatrics University of Texas Health Science Center at Dallas Southwestern Medical School, Dallas, Texas, 25-26 May 1988

Bass JW: Purulent Meningitis: Pitfalls in Diagnosis and Management; Pertussis and Look-a-Like Diseases; Infectious Diarrhea. Guest Faculty, Eleventh Annual Black Hills Seminar on Advances in Clinical Pediatrics, Sylvan Lake Resort, South Dakota, 22-24 June 1988

Bass JW: Pertussis, Streptococcal and Hemophilus Influenzae Infections. Visiting Lecturer, Tropical Medicine Course, Walter Reed Army Institute of Research, Washington, D.C., 9 August 1988

Bass JW: Streptococcal Pharyngitis: Update. Guest Faculty, American College of Physicians Conference, San Francisco, California, 20-23 October 1988

Bass JW: Program Director, 24th Uniformed Services Pediatric Seminar Honolulu, Hawaii, 19-23 March 1989

Bass JW: Occult Bacteremia, Pertussis: Past, Present and Future, Infectious Diarrhea: Update, Hemophilus Influenzae B Infections, Diagnosis and Treatment. Guest Faculty, American Academy of Pediatrics Second Annual Pediatrics in Progress, Las Vegas, Nevada, 14-16 April 1989

Nomizu S, Person DA, Saito CK, Lockett LJ: A Unique Case of Reducing Body Myopathy. An Asso of Electromyography and Electrodiagnosis Meeting, Washington DC, September 1989

Parsons MK: Acute Shift of Right Ventricular Distensibility After Balloon Pulmonary Vavuloplasty. American Heart Association Scientific Sessions Program, 14-17 November 1988

Parsons MK: Echocardiographic Determination of Critical Left Ventricular Size in Infants with Isolated Aortic Valve Stenosis, American Heart Association Scientific Sessions Program, 14-17 November 1988

Pichoff BE, Schydlower M, Stephenson SR: Military Dependent Children at Risk for Accidental Hot Tap Water Burns. William Beaumont Army Medical Center, El Paso, Texas, 21-26 October 1989

## DEPARTMENT OF PSYCHIATRY

Evans GD: The Use of Antidepressants in the Treatment of Chronic Pain, Tripler AMC, 23 May 1989

Evans WS, Black SA: A Comparison of Brief Group Therapies for Preschool Children: Parent Training vs Group Play Therapy vs Project Group. Military Conference on Child and Family Psychiatry, Reno, Nevada, February 1988

## DEPARTMENT OF RADIOLOGY

Johnson JF, Coughlin WF: Sensitivity of Plain Films in the Detection of Appendiceal Perforation in Children. Presentation at the 73rd Scientific Assembly and Annual Meeting of the Radiological Society of North America, Chicago, Illinois, December 1988

Shiels WE, Babcock DS, Wilson JL, Burch R: Sonographic Localization and Guided Removal of Soft Tissue Foreign Bodies. Presentation at the Society of Pediatric Radiology, San Antonio, Texas, 6 April 89

## DEPARTMENT OF SURGERY

### General Surgery Service

Barcia PJ: Four surgical advances from the TAMC General Surgery Residency. Shogun Medical Society, Honolulu, Hawaii, 23-25 May 1988

Barcia PJ, Laberge J: Management of Oriental Cholangiohepatitis: A new approach. Shogun Medical Society, Honolulu, Hawaii, 23-25 May 1988

Barcia PJ: Pilonidal Sinus Disease: Conservative Rx. Shogun Medical Society, Honolulu, Hawaii, 23-25 May 1988

Beresky RE, Olson D, Huang YC, Barcia PJ: Abdominal Aortic Transection Secondary to Blunt Trauma in a Child. Shogun Medical Society, Honolulu, Hawaii, 23-25 May 1988

Dixon JW, Lisehora G, Lee YTM: Common Bile Duct Carcinoid Tumor. 38th Parallel Medical Society Meeting, Seoul Korea, 15-17 November 1989

Dixon JW, Martin R: Extrahepatic Bile Duct Injury from Blunt Abdominal Trauma. 38th Parallel Medical Society Meeting, Seoul Korea, 15-17 November 1989

Fengler SA, Berenberg JL, Lee YTM: Disseminated Coagulopathies and Advanced Malignancies. Hawaiian Chapter, American College Surgeons, 12 June 1989



Fengler SA, Berenberg JL, Lee YTM: Disseminated Coagulopathies and Advanced Malignancies. G. P. Wratten Surgical Symposium, Bethesda, Maryland, 30-31 March 1988

Fengler SA, Sheridan MF, Rodriguez A: Recurrent Midgut Volvulus in the Adult. Gary P. Wratten Surgical Symposium, Madigan AMC, 10-13 April 1989

Humphrey WT, Rudolph C, Barcia PJ: Toxic Shock Syndrome in the Postoperative Patients. Gary P. Wratten Surgical Symposium, Madigan AMC, 10-13 April 1989

Knuth TE, Laberge JM, Barcia PJ: New Approaches to Enteral Nutrition in Patients with Complicated Bowel Fistula. William Beaumont GI Symposium, San Francisco, California, 23-26 October 1988

Knuth TE, Laberge JM, Barcia PJ: Percutaneous Approaches to Enteral Nutrition in Patients with Complicated Bowel Fistula. G. P. Wratten Surgical Symposium. Bethesda, Maryland, 30-31 March 1988

Lee YTM: Melanoma: Clinical Presentations and RX. Marion S. DeWeese Surgical Society, San Diego, California, 2-5 March 1988

Lee YTM: Diagnosis and Treatment of Malignant Melanoma. Weekly Medical Staff Conference, Wahiawa General Hospital, Honolulu, Hawaii, 22 November 1988

Lee YTM: Surgical Incisions and Decisions. TAMC Soft Tissue Workshop, 19 January 1989

Lee YTM: Planning the Direction of Incisions. TAMC Soft Tissue Workshop, 21 January 1988

Leshner SDH, Barcia PJ: Urinary D-Lactate: A Specific Indicator of Intestinal Ischemia. Gary P. Wratten Surgical Symposium, Madigan AMC, 10-13 April 1989

Leshner SDH, Huang YC: Diagnosis and Treatment of Anorectal Malformations: Gary P. Wratten Surgical Symposium, Madigan AMC, 10-13 April 1989

Leshner SDH, Lee YTM: Acute Pancreatitis in a Military Hospital. Marion S. DeWeese Surgical Society, San Diego, California, 2-5 March 1988

Lisehora GE, Barcia PJ: Fitz-Hugh-Curtis Syndrome: A Rare Diagnosis in a Not So Rare Condition. Hawaiian Surgical Association, Oahu, Hawaii, 6 August 1988

Lisehora GE, Lee YTM, Barcia PJ: Tuberculous Peritonitis: A Condition Still Needs Laparotomy for Diagnosis. Hawaiian Chapter, American College Surgeons, Honolulu, Hawaii, 13 June 1988

Napoli PJ: Fungal Endocarditis and Mycotic Aneurysm. Hawaiian Surgeons Association Meeting, Molokai, Hawaii, 4-6 August 1989

Rudolph C: Limited Ligation and Stripping as the Preferred Method of Treating Varicose Veins. G. P. Wratten Surgical Symposium, Bethesda, Maryland, 30-31 March 1988

Rudolph C: Omental Infarction. Hawaiian Surgical Association, Oahu, Hawaii, 6 August 1988

Rudolph C, Kennon W: Chylous Ascites: A Case Report. Gary P. Wratten  
Surgical Symposium, Madigan AMC, 10-13 April 1989

Schatz D., Lee YTM: Gastrointestinal Malignant Melanoma. William Beaumont GI  
Symposium, San Francisco, California, 23-26 October 1988

Schuchmann GD, Barcia PJ: Phosphate Absorption after Fleet Enemas  
Administration in Adults. Society University Surgeon, 10 February 1988

Tomaski S: Basal Cell Nevus Syndrome. 38th Parallel Medical Society, Seoul,  
Korea, 22 November 1988

Watts DM, Lee YTM: Non-Osseous Sarcoma: A Fifteen Year Review. G. P.  
Wratten Surgical Symposium, Bethesda, Maryland, 30-31 March 1988

Watts DM, Rudolph CC, Rodriguez A: Alternatives to Permanent Ileostomy in  
Ulcerative Colitis Patients. Hawaiian Surgeons Association Meeting, Molokai,  
Hawaii, 4-6 August 1989

#### Orthopedic Surgery Service

Albertson K: Multiple Volar Carpometacarpal Dislocations in an Athlete.  
Fourth Annual Combined Spring Orthopaedic Symposium, Turtle Bay Hilton,  
Hawaii, 10 June 1989

Bendowski TF: Arthroscopic Subacromial Decompression: Short Term Followup in  
Fourteen Patients. 30th Annual Meeting of the Society of Military Orthopaedic  
Surgeons, Williamsburg, Virginia, 5-9 December 1988

Fay MJ: Arthroscopic Assisted Reconstruction of the Anterior Cruciate  
Ligament Using Patellar Tendon Allograft. American Physical Therapists  
Association, Hilton Hawaiian Village, Honolulu, Hawaii, 3 February 1989

Fay MJ: Comparison of Anterior Cruciate Repair: Open vs. Arthroscopic, The  
Perioperative Period. Letterman Army Medical Center, Orthopaedic Surgery  
Service, San Francisco, California, 21 July 1989

Fay MJ: Acute PCL Insufficiency in Children. Letterman Army Medical Center,  
Orthopaedic Surgery Service, San Francisco, California, 21 July 1989

Fugate DS, Romash MM: Passive Range of Motion of the Great Toe Metatarsal,  
Preoperative Assessment. Am Ortho Foot and Ankle Soc Meeting, Las Vegas,  
Nevada, February 1989

Fugate DS: Passive ROM of the First Ray Prior to Bunion Surgery. Fourth  
Annual Combined Spring Orthopaedic Symposium, 10 June 1989

Hynes RA, Ma G: Percutaneous Tendo Achilles Repair: A Ten-Year Review of the  
Ma Technique. 38th Parallel Medical Society Meeting, Hyatt Regency Hotel,  
Seoul, Korea, 16 November 1988

Hynes RA, Ma G: Percutaneous Tendo Achilles Repair: A Ten-Year Review. 8th Annual Trauma Symposium, William Beaumont Army Medical Center, El Paso, Texas, 19 November 1988

Hynes RA, Ma G: Percutaneous Tendo Achilles Repair: A Ten-Year Review of the Ma Technique. 30th Annual Meeting of the Society of Military Orthopaedic Surgeons, Williamsburg, Virginia, 5-9 December 1988

Hynes RA, Ma G: Percutaneous Tendo Achilles Repair: A Ten-Year Review of the Ma Technique. Specialty Day of the American Orthopaedic Society for Sports Medicine, Las Vegas, Nevada, 12 February 1989

Hynes RA; Ma G: Poster Exhibit .f Percutaneous Tendo Achilles Repair - A Ten-year Review of the Ma Technique. 56th Annual Meeting of the American Academy of Orthopaedic Surgeons, Las Vegas, Nevada, 13 February 1989

Ono CM: Operative Length Change in Idiopathic Scoliosis. Fourth Annual Combined Spring Orthopaedic Symposium, Turtle Bay Hilton, Makaha, Hawaii, 10 June 1989

Ono CM, Reinker KA, Vanscoy SV, Jones DA: Operative Length Change in Scoliotic Spines, Resident Essay Competition, Waikiki, Hawaii

Person DA, Reinker KA: Johnny Won't Walk: Pitfalls in Diagnosis of Joint Complaints. 24th Annual Uniformed Services Pediatric Seminar, Honolulu, Hawaii, 22 March 1988

Pitcher JD: Displaced Femoral Stress Fractures: A Retrospective Study of Their Prevalence. 121st Evac Hospital Korea, 13 September 1988

Pitcher JD: Displaced Femoral Stress Fractures: A Retrospective Study of Their Prevalence. 38th Parallel Medical Society Meeting, Hyatt Regency Hotel, Seoul, Korea, 16 November 1988

Pitcher JD: Comparison of Anterior Cruciate Ligament Repair: Arthroscopy and Arthrotomy. AOA Residents Conference, Rochester, New York, 29 March - 1 April 1989

Pitcher JD: Comparison of Anterior Cruciate Ligament Repair: Arthroscopy and Arthrotomy Perioperative Comparison. Hawaii Orthopaedic Association Meeting, Turtle Bay, Hawaii, 9 June 1989

Pitcher JD. Arthroscopic Anterior Cruciate Repair. 4th Annual Combined Spring Orthopaedic Symposium, Turtle Bay Hilton, Makaha, Hawaii, 9 June 1989

Reesor KE: Intrapelvic Leg Lengthening. 4th Annual Combined Spring Orthopaedic Symposium, Turtle Bay Hilton, Hawaii, 10 June 1989

Reinker KA, Ono CM, VanScoy S: Operative Length Change in Scoliotic Spines, Shriners Hospital for Crippled Children Chiefs of Staff Meeting, Springfield, Massachusetts, 5-8 October 1988

Reinker KA, Jones RD: Vertebral Infections: A Clinical Review. 30th Annual Meeting of the Society of Military Orthopaedic Surgeons, Williamsburg, Virginia, 5-9 December 1988

Reinker KA: Anesthesia and the Repair of Extremity Injuries. Soft Tissue Surgery Workshop at Tripler Army Medical Center, Honolulu, Hawaii, 20 January 1989

Reinker KA: Biomechanics, Dynamics of Joint Motion. University of Hawaii Integrated Orthopaedic Surgery Residency Training Program, Honolulu, Hawaii, 28 February 1989

Reinker KA: Basic Science of Bone Dysplasias. 17th Annual Symposium of Children's Orthopaedics at Fitzsimmons Army Medical Center, Aurora, Colorado, 8-10 March 1989

Reinker KA: Pediatric Athletic Injuries. 24th Annual Uniformed Services Pediatric Seminar, Honolulu, Hawaii, 22-23 March 1989

Reinker KA: Biomechanics. University of Hawaii Integrated Orthopaedic Surgery Residency Training Program. Honolulu, Hawaii, 6, 21, and 28 March 1989

Reinker KA: Orthopaedic Biomechanics I - Properties of Materials. 40th Annual Military Surgical Clinical Congress, Garmish, Germany, 22-25 May 1989

Reinker KA: Orthopaedic Biomechanics II - Fracture Biomechanics. 40th Annual Military Medical Surgical Clinical Congress, Garmish, Germany, 22-25 May 1989

Reinker KA: Pediatric Sports Medicine. 40th Annual Military Medical Surgical Clinical Congress, Garmish, Germany, 22-25 May 1989

Reinker KA: Metabolic Bases of Bone Dysplasia. 4th Annual Combined Spring Orthopaedic Symposium, Turtle Bay Hilton, Makaha, Hawaii, 9 June 1989

Romash MM, Fugate DS: Passive Range of Motion of the Great Toe Metatarsal, Preoperative Assessment, 19th Annual Meeting of the American Orthopaedic Foot and Ankle Society, 12 February 1989

Romash MM, Henningson HJ, Claybaugh J: Knee Braces: Comparative Functional Testing, Scientific Program of the 56th Annual Meeting American Academy of the Orthopaedic Surgeons, Las Vegas, Nevada, 9 February 1989

Rungee JL: Acute PCL Insufficiency in Children. 4th Annual Combined Spring Orthopaedic Symposium, Turtle Bay Hilton, Hawaii, 9 June 1989

Rungee JL, Fay MJ: Acute Posterior Cruciate Ligament Insufficiency in Children: Two Case Reports and Literature Review. Soc of Milit Ortho Surg, San Antonio, Texas

Schmidt DM: Ankle Arthroscopy--The Tripler Experience. 4th Annual Combined Spring Orthopaedic Symposium, Turtle Bay Hilton, Hawaii, 9 June 1989

Schmidt DM: Ankle Arthroscopy. Annual Essay Competition sponsored by the Hawaii Chapter of the American College of Surgeons, 12 June 1989

Yanklowitz BAD: Large Unicameral Bone Cyst of the Calcaneus with Iliac Bone Graft - A Case Report, USAF Podiatry Conference, Langley Air Force Base, Virginia, 14-16 March 1989

Yanklowitz BAD: Common Podiatric Conditions. Troop Medical Command at Kaneohe Marine Corps Air Station, 28 June 1989

### Otolaryngology Service

Lunde KC: Merkel Cell Carcinoma: A Case Report and Literature Review. Am Acad of Oto-Head and Neck Surg, New Orleans, Louisiana, 24-28 September 1989

Lunde KC: Granular Myringitis, Am Acad of Oto-Head and Neck Surg, New Orleans, Louisiana, 24-28 September 1989

Souliere CR: Selective Medical Therapy for Subperiosteal Abscess of the Orbit. ASPO Meeting, San Diego, California, May 1989

Souliere CR, Kava CF: Sudden Hearing Loss as the Sole Manifestation of Neurosarcooidosis. Am Acad of Oto-Head and Neck Surg, New Orleans, Louisiana, 24 September 1989

Yim DWS: The External (combination) Rhinoplasty Approach Access for Management of the Problem Nasal Deformity, Am Acad of Oto-Head and Neck Surg, New Orleans, Louisiana, 24 September 1989

Yim DWS, Zieske LA: Open Rhinoplasty Approach for Transseptal Sphenoid Sinus and Transsphenoidal Surgery, Am Acad of Oto-Head and Neck Surg, New Orleans, Louisiana, 24 September 1989

Zieske LA: Frozen Section Considerations for Basal and Squamous Cell Skin Malignancies. Symposium on Facial Skin Malignancies, San Antonio, Texas, November 1988

Zieske LA: Bipolaris Fungal Sinusitis. International Symposium on Infection and Allergy of the Nose. International Rhinology Conference, Baltimore, Maryland, June 1989

Zieske LA, Raterink MH, Kopke RD: Bipolaris Paranasal Sinusitis. PCOOS Meeting, Kauai, Hawaii, June 1989

Zieske LA, Kopke RD: Bipolaris Fungal Sinusitis. Am Acad of Oto-Head and Neck Surg, New Orleans, Louisiana, 24-28 September 1989

### Urology Service

Allen RC, Kennon WG: Intravesical Hemorrhage Following Transrectal Prostate Biopsy. 36th Kimbrough Urological Seminar, Norfolk, Virginia, November 1988

Allen RC: Prostatic Abscess. TDY Presentation (abstract) 37th Kimbrough Urological Seminar, San Antonio, Texas, 3-8 December 1989

Crain TW, Wikert GA, Kreder KJ, Pliskin MJ, Dresner ML: Early Clinical Experiences with Candela Pulsed Dye Laser. 36th Kimbrough Urological Seminar, Norfolk, Virginia, November 1988

Desmond PM, Hassell LH, Wikert GA, Pliskin MJ: The Role of ADH, Renin, Aldosterone and Human Atrial Natriuretic Factor (hANF) in TUR Syndrome. Kimbrough Urologic Seminar, Norfolk, Virginia, November 1988

Dresner ML: Cryptorchidism. American College of Osteopathic Meeting, Honolulu, Hawaii, October 1987

Dresner ML, Sateri F, Kreder KJ, Shavver TR, Huang YC: Urachal Extrophy presented at the Kimbrough Urologic Seminar, Washington D.C., November 1987

Dresner ML, Kennon WG, Wikert GA: Technical Aspects of Open Urethroplasty. 36th Kimbrough Urological Seminar, Norfolk, Virginia, November 1988

Dresner ML, Kennon WG, Wikert GA: Technical Aspects of Open Urethroplasty. Henry Ford Hospital, Detroit, Michigan, November 1988

Dresner ML: Cryptorchidism. Hot Spots in Pediatric Urology, Kauai, Hawaii, March 1989

Desmond PM, Hassell LH, Claybaugh JR, Wikert GA: The Roles of ADH, ANF, Renin, and Aldosterone in the Transurethral Resection (TUR) Syndrome. Federation of American Societies for Experimental Biology, New Orleans, Louisiana, March 1989

Dresner ML, Wikert, GA: Human Umbilical Vein Graft as a Catheterizable Continent Stoma in the Pig. American Urological 84th Annual Meeting, Dallas, Texas, May 1989

Dresner ML: Prostate Cancer. Hickam Air Force Base Clinic, Honolulu, Hawaii, June 1989

Dresner ML: Acute Scrotum and Other Emergencies. Schofield Clinic, Wahiawa, Hawaii, August 1989

Desmond PM, Dresner ML, Kreder KJ: Penile Carcinoma: Case Report in a Circumcised Male. Kimbrough Urologic Seminar, Washington D.C., November 1987

Desmond PM: Single Nephrostomy Treatment of Staghorn Calculi. TDY Presentation (abstract) 37th Kimbrough Urological Seminar, San Antonio, Texas, 3-8 December 1989

Kennon WG: Advances in the Diagnosis of Hematuria. American College of Osteopathic Meeting, Honolulu, Hawaii, October 1987

Kennon WG: Diphosphonate Therapy for Metastatic Prostate Cancer. Kimbrough Urologic Seminar, Washington D.C., November 1987

Kennon WG: Use of the Autoanalyser to Determine Red Cell Morphology and Etiology in the Diagnosis of Hematuria. 36th Kimbrough Urological Seminar, Norfolk, Virginia, November 1988

Kennon WG: Long Term Follow-up in the Military: A Guide to Finding the "Lost" Patient. TDY presentation (abstract), 37th Kimbrough Urological Seminar, San Antonio Texas, 3-8 December 1989

Kreder KJ, Dresner ML: Testicular Tumors of Childhood. American College of Osteopathic Surgeons meeting, Honolulu, Hawaii, October 1987

Kreder KJ, Dresner ML: The XX Male Syndrome. Kimbrough Urologic Seminar, Washington D.C., November 1987. Presented at Chief Residents Conference, Newport, Rhode Island, May 1988

Morey AF: Fertility Issues in the Therapy of Early Stage Seminoma. TDY Presentation (abstract) 37th Kimbrough Urological Seminar, San Antonio, Texas, 3-8 December 1989

Pliskin MJ: Inadvertent Urethral Insertion of a Contraceptive Suppository. Kimbrough Urologic Seminar, Washington, D.C., November 1987

Pliskin MJ, Kreder KJ, Wikert GA, Dresner ML: Human Umbilical Vein Graft as a Catheterizable Continent. Am Uro Asso Meeting, Dallas, Texas, February 1989

Raterink MH: Recurrent Acute Parotitis in an Immunocompromised Patient. ASPO Meeting, San Diego, California, May 1989

Wikert GA, Kreder KJ, Dresner ML: Extracorporeal Shock Wave Lithotripsy and Adult Polycystic Kidney Disease. Kimbrough Urologic Seminar, Washington D.C., November 1987

Wikert GA: Intrahepatic Applications of Endourology. TDY Presentation (abstract) 37th Kimbrough Urological Seminar, San Antonio, Texas, 3-8 December 89

### Detail Summary Sheet

Prot No: 41A86	Status: Ongoing
TITLE: Effects of Elevated Mineralocorticoid on Blood Pressure, Thirst, and Vasopressin Responses to Angiotensin in the Goat	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: CPT Beau J. Freund, MS; Aileen K. Sato; MAJ Albert H. McCullen, VC	
Department/Section: Clinical Investigation/Physiology	
Key Words: mineralocorticoid; vasopressin; angiotensin;	
Funding: FY 88: \$16,128. FY 89: \$23,373.	Periodic Review Date: Sep 89
Gifts: VA/DOD Grant Awarded	Decision: Continue

**OBJECTIVE:** To determine if the vasopressin (VP) response to angiotensin II is enhanced by previous administration of aldosterone, and whether the VP responses to central or peripheral administration of angiotensin II are differentially affected by the aldosterone treatment.

**TECHNICAL APPROACH:** Goats will be surgically prepared with chronic and indwelling cannula in the lateral ventricle of the brain and a carotid arterial loop. After two weeks of aldosterone or vehicle injections, the responsiveness to angiotensin II will be determined. The angiotensin will be administered IV or into the lateral ventricle of the brain. The blood pressure, thirst, and CSF and plasma ADH responses will be determined.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Prior administration of mineralocorticoid (DOCA), as expected reduces resting levels of plasma renin activity (PRA). We also observed a significant increase in atrial natriuretic factor (ANF). Peripheral iv administration of angiotensin II (n=6) significantly reduced PRA, and increased ANF, vasopressin, and blood pressure in goats with and without prior DOCA administration. Prior DOCA administration increased the blood pressure response and reduced the vasopressin response to iv angiotensin II. Intracerebroventricular angiotensin II stimulated vasopressin, and increased blood pressure and decreased ANF (n=4), but no differences in these responses appears to be affected by prior administration of DOCA. Samples have been set aside for ACTH analysis. Consistent with previous reports, prior DOCA administration does appear to "up-regulate" angiotensin II receptors in the vasculature since AII produced a greater increase in blood pressure after DOCA administration. However, we found no "up regulation" of centrally mediated AII response or peripheral AII effects on hormones. Publication: Claybaugh JR, Sato AK, Freund BJ, McCullen AH: Effects of Prior Mineralocorticoid (DOCA) Administration on ADH Responses Intracerebroventricular (ivt) or iv Angiotensin II. FASEB J 3:A246, 1989 (Abs #113).



### Detail Summary Sheet

Prot No: 11A87

Status: Ongoing

TITLE: The Metabolic Clearance of Arginine Vasopressin in the Amniotic Sac of the Fetal Guinea Pig

Principal Investigator: John R. Claybaugh, Ph.D.

Associate Investigators: MAJ Gerard Letterie, MC; Aileen K. Sato;

Department/Section: Clinical Investigation/Physiology

Key Words: arginine vasopressin;

Funding: FY 88: \$1,273. FY 89: \$264. Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** To demonstrate that the amniotic sac is a major site of fetal AVP clearance. Further, we will determine where in the amniotic sac AVP metabolism occurs (via amniotic fluid enzymes and/or via amnionic membrane receptors), explore the kinetics of this metabolic process, and characterize the metabolites produced.

**TECHNICAL APPROACH:** Vasopressin, either unlabelled or labelled with tritium-will be injected into the amniotic sac while the maternal guinea pig is under anesthesia and the fate of the vasopressin relative to insulin will be assessed by HPLC and radioimmuno assay. In vitro experiments will be conducted to determine the sites of vasopressin metabolism and action.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

We have determined for the first time that: Vasopressin is metabolized into two major products in the amnionic sac. One product has been determined to be des-gly arginine vasopressin, and the enzyme responsible is most like trypsin. This is the first description of metabolism of vasopressin by a trypsin-like enzyme. This enzyme is in the amnionic fluid, and not identifiable in the amnionic membrane. The other metabolic product is as yet not identified, nor is the enzyme. Interestingly, it is usually not found in the amnionic fluid and is always found in the amnionic membrane. This year the following publications have resulted from this protocol:

Uyehara, CFT, and JR Claybaugh. Vasopressin metabolism in the amnionic sac of the fetal guinea pig. Endocrinology 123:2040-2047, 1988.

Uyehara, CFT, Sato AK, Claybaugh JR: Vasopressin is Metabolized by a Trypsin-like Enzyme in Guinea Pig Amnionic Fluid. Am J Physiol (Endocrinol Metab) (in press)(Sep 89).

### Detail Summary Sheet

Prct No: 1A88

Status: Ongoing

TITLE: Effects of Des-leu Angiotensin I, Cortisol, and Hyperbaria on the Release of Vasopressin from the Isolated Hypothalamoneurohypophyseal System

Principal Investigator: John R. Claybaugh, Ph.D.

Associate Investigators: Aileen K. Sato, Med. Tech;  
Glenn M. Hashiro, Biol. Lab Tech.;  
CPT Beau J. Freund, MSC; David G. Changaris, MD;  
Suk Ki Hong, MD, Ph.D.; Wayne Ichimura, Biomedical  
Engr.

Department/Section: Clinical Investigation/Physiology

Key Words: des-leu angiotensin I;

Funding: FY 88: \$6,243. FY 89: \$19,481.

Periodic Review Date: Sep 89

Gifts: VA-DOD Grant

Decision: Continue

**OBJECTIVE:** 1) To determine if des-leu angiotensin I is able to stimulate vasopressin from the isolated hypothalamoneurohypophyseal system (HNS) in a manner similar to angiotensin II. 2) To determine if cortisol can inhibit baseline or stimulated vasopressin release from the HNS. 3) To determine if hyperbaria will inhibit the release of vasopressin from the HNS. To determine if des-leu angiotensin I stimulates vasopressin release in conscious goats and the control mechanism of the response.

**TECHNICAL APPROACH:** Two approaches to isolated hypothalamoneurohypophyseal explants have been followed, a tissue incubation (acute) and a tissue culture (chronic) approach. Both involve the surgical removal of the floor of the brain of the rat, a triangular piece of tissue approximately 1 mm thick, with a base extending parallel and anterior to the optic chiasma, and the apex approximately 2 mm posterior to the stalk of the neurohypophysis. The anterior pituitary is removed. The resulting tissue block includes the supraoptic nucleus with intact axonal projections through the stalk to the neurohypophysis. We have also begun studies on the central (intracerebroventricular) administration of angiotensin II and des-leu angiotensin I.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The chronic preparation of the HNS, although preferred, is still not functional. We have been able to stimulate vasopressin release with .00005 M angiotensin II, and with a an osmotic stimulation of 400 mOsm/kg H<sub>2</sub>O in the media, and with 56 mM KCl. des-leu Angiotensin II appears to be an order of magnitude less sensitive in the stimulation of vasopressin. We have initiated studies on the cortisol effects of angiotensin and osmotically stimulated vasopressin release. At this time, with 10 preparations observed, cortisol has no effect. We have found that des-leu angiotensin I does stimulate vasopressin release in the conscious goat. It is also 10 times less potent than angiotensin II.

### Detail Summary Sheet

Prot No: 20A88	Status: Ongoing
TITLE: Stop-flow Analysis of Sodium Entry and Tubular Transit Times for Sodium and Inulin in Normal and Nephrotic Rats	
Principal Investigator: John R. Claybaugh, Ph.D. (formerly: Ralph Keeler, Ph.D.)	
Associate Investigators: Ms. Aileen K. Sato	
Department/Section: Clinical Investigation/Physiology	
Key Words: vasopressin (ADH);	
Funding: FY 88: \$3,084. FY 89: \$1,824.	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** The purpose of the proposed experiments is to extend our current investigations on the effects of atrial natriuretic peptides (ANP) on sodium transport in kidneys as follows: (1) To use "stop-flow" analysis in an attempt to locate the tubular level at which extra-luminal sodium enters the nephron. (2) To measure the effects of ANP on simultaneous indicator dilution curves for sodium and inulin in a rat model of an ANP-resistant salt and water retaining state (Adriamycin nephrosis) using innervated or denervated kidneys.

**TECHNICAL APPROACH:** Because of  $^{22}\text{Na}$  disposal problems possibly occurring, the more difficult approach utilizing an isolated kidney was developed. The first steps in validating the function of the kidney included the clearance of creatinine, Na, and K, and the determination of effects of vasopressin and its clearance. This has yielded interesting results regarding vasopressin clearance which we are presently pursuing before continuing on to the original sodium handling questions we were after.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Progress (through August 88): To date we have successfully developed an isolated perfused rat kidney preparation that is physiologically functional for a period of about two hours. This is in agreement with previous publications. We have established that these kidneys are responsive to vasopressin in that they produce a more concentrated urine when vasopressin is in the media. We have also determined that vasopressin is metabolized by at least two mechanisms in this preparation. First via filtration and excretion, but approximately 10 fold more via other renal mechanisms presumably in the vasculature. When a  $V_2$  vasopressin antagonist was added to the medium, the peritubular clearance of vasopressin was inhibited by 75%, but the urinary clearance was not significantly affected.

Keeler R, Sato AK, Claybaugh JR: Effect of  $V_2$  antagonist on the Clearance of vasopressin by Isolated Perfused Rat Kidneys.<sup>2</sup> FASEB J 3:A246, 1989 (Abs #112).

### Detail Summary Sheet

Prot No: 13A89	Status: Ongoing
TITLE: Effects of Hyperoxia on Airway Smooth Muscle Function in Newborn Guinea Pigs	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Kenneth T. Nakamura, M.D.; MAJ W. Michael Southgate, MC; Linda Kullama, Ph.D.	
Department/Section: Clinical Investigation/Physiology	
Key Words: hyperoxia;	
Funding: FY 88: NA	FY 89: \$11,415
Gifts: Grant *	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine if generalized or selective change of newborn guinea pigs airway smooth muscle responsiveness occurs in oxygen-induced injury. We will examine contractile and relaxation responses of isolated newborn guinea pig tracheal smooth muscle rings following randomization to room air or 95% oxygen for 2 days.

TECHNICAL APPROACH: Guinea pigs will be euthanized and trachea/bronchi will be removed. Isometric force will be recorded using standard organ tissue baths with rings bathed in Kreb's solution at T 37° with 95% O<sub>2</sub> - 5% CO<sub>2</sub>. Agonists and antagonists will be added to the muscle bath and tension recorded via a Grass FT .03 force-displacement transducer coupled to a Gould recorder. Tissue will be examined histologically employing standard H & E staining and Giemsa stains.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Preliminary data suggest:

- 1) Newborn guinea pig airways may be more sensitive and develop greater tension per tissue weight compared to adults with histamine and acetylcholine stimulation.
- 2) The effect of epithelium removal on these responses are minimal.
- 3) Atrial natriuretic factor produces relaxation of airway smooth muscle, and is more effective following histamine contraction versus acetylcholine.

\*Research Corporation of the University of Hawaii Leahi Trust

### Detail Summary Sheet

Prot No: 21A89	Status: Ongoing
TITLE: Effects of Hypoxia on the Vasopressin Response to Hemorrhage and its Role in the Maintenance on Blood Pressure	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Mark R. Eichinger, Graduate Assistant, Ph.D. Student	
Department/Section: Clinical Investigation/Physiology	
Key Words: hypoxia; vasopressin;	
Funding: FY 88: NA	FY 89: \$7,911. Periodic Review Date: Sep 89
Gifts: MRDC Grant	Decision: Continue

OBJECTIVE: There is reason to believe that the maintenance of basal blood pressure and blood pressure in response to hemorrhage would be altered during conditions of hypoxemia. Similarly, pulmonary arterial blood pressure is altered during hypoxia. We propose to determine if an altered vasopressin response or vascular responsiveness is in part responsible. In addition to volume control, osmotic control of vasopressin may be altered during hypoxia. This too, will be investigated.

TECHNICAL APPROACH: We have chosen the conscious adult goat as our animal model. All animals to be employed in the study must first undergo surgical procedures for the construction of a carotid artery loop and tracheal fistula. The carotid artery loop allows for both blood sampling and the means of blood withdrawal during the hemorrhage studies. The fistula is used to make the animal hypoxemic by introduction of nitrogen through a tracheal catheter. The level of hypoxemia is determined through blood gas analysis, and radioimmunoassays are employed for measurement of hormonal changes.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date, four goats have undergone the above mentioned surgical procedures, and two have been run in trial experiments. In the course of the trial experiments, some necessary changes became obvious. An addendum to the protocol has been submitted to account for these changes (i.e. tracheal catheter and utilization of only nitrogen vs. tracheostomy and a closed loop system). The two animals run in the trial experiments were successfully made hypoxemic. Further, analysis of blood samples revealed an expected increase in plasma concentrations of vasopressin. These preliminary findings are promising, and work is proceeding in fully implementing protocol 21A89.

### Detail Summary Sheet

Prot No: 36A89	Status: Ongoing
TITLE: Ontogeny of the Mechanisms of Arginine Vasopressin and Vasotocin Mediated Contraction	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Linda K. Kullama, Ph.D., Dr. Kenneth T. Nakamura, MD; Dr. Venkataraman Balaraman, MD, Wayne M. Ichimura, Biomedical Engineer.	
Department/Section: Clinical Investigation/Physiology Service	
Key Words: arginine vasopressin; vasotocin;	
Funding: FY 88: NA	FY 89: \$15,104.
Gifts: grant*	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To define the ontogeny of the mechanism(s) of arginine vasopressin (AVP) and arginine vasotocin (AVT) mediated contraction as compared to norepinephrine (NE) mediated contraction.

**TECHNICAL APPROACH:** We are using invitro isometric tension measurements of the contractile response of rings of rat thoracic aorta in the presence and absence of Ca blockers and Ca-free solutions. We will be utilizing <sup>45</sup>Ca in in vitro experiments using similar composition solutions - this portion has not been started yet.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Thus far we have determined that vasopressin mediated contraction is partially dependent on intracellular calcium release and is not totally dependent on the presence of extracellular calcium; a report to the effect that it is completely extracellular calcium dependent is in the literature. Thus our initial results refute this report. There is some indication that Ca blockers are somewhat more effective in adult rat aorta than in 1 week rat aorta. Thus far the proportion of the contractile response blocked by Ca antagonists appears similar for norepinephrine and vasopressin mediated contraction.

\* American Heart Association Fellowship Grant

### Detail Summary Sheet

Prot No: 52A89

Status: Ongoing

TITLE: Effects of Vasopressin on Pulmonary Vascular Resistance in Hypoxia Induced Pulmonary Arterial Hypertension in Newborn and Adult Pigs

Principal Investigator: John R. Claybaugh, Ph.D.

Associate Investigators: MAJ Mark K. Parsons, MC; Catherine F.T. Uyehara, Ph.D.  
Kenneth T. Nakamura, MD; Mark Eichinger;  
CPT Beau J. Freund, MS; Aileen K. Sato;  
Glenn M. Hashiro;

Department/Section: Clinical Investigation/Physiology Section

Key Words: vasopressin; hypoxia;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: \$25,000. Leahi Trust

Decision: Continue

**OBJECTIVE:** To determine the vasopressin response of the pig to acute hypoxic exposure (i.e. 10% inspired  $O_2$ ) and characterize this response in pigs of ages ranging from newborn to 3 months. We will also assess the atrial natriuretic peptide responses in the same series. To determine the pulmonary arterial pressure and pulmonary vascular resistance (PVR) response of the newborn pig to hypoxia. To determine the pulmonary arterial pressure and PVR responses to vasopressin or atrial natriuretic peptide of the pig. To determine the sensitivity of the hypoxia induced pulmonary arterial hypertension and PVR to  $V_1$  and  $V_2$  receptor blockade.

**TECHNICAL APPROACH:** Two to three day old pigs will be anesthetized and catheterized with a Swan-Ganz catheter to determine pulmonary arterial and wedge pressures and cardiac output. They may also have to have the ductus arteriosus ligated. A hypoxic gas, 10%  $O_2$ , will be administered by tracheal tube, and the pulmonary vascular resistance monitored. Vasopressin will be measured prior to hypoxia and during hypoxia and  $V_1$  and  $V_2$  blockers will be administered to assess the role of vasopressin receptors in the increased pulmonary vascular resistance response to hypoxia.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

We are awaiting the arrival of Catherine F. T. Uyehara, Ph.D. to conduct the studies.

### Detail Summary Sheet

Prot No: 541189\* Status: Ongoing

TITLE: Responses of Water and Electrolyte Regulating Hormones During a Saturation Dive to 450M

Principal Investigator: John R. Claybaugh, Ph.D.

Associate Investigators: Peter B. Bennett, Ph.D.; Richard E. Moon, MD; Suk Ki Hong, MD, Ph.D.; James Goldinger, Ph.D.

Department/Section: Clinical Investigation/Physiology Section

Key Words: electrolyte;

Funding: FY 88: NA FY 89: \$705. Periodic Review Date: Sep 89

Gifts: NIH Decision: Continue

**OBJECTIVE:** Document diuresis in Trimix 450 M dive and to determine whether there is an alteration in the circadian pattern of urine flow and/or excretion of electrolytes. To determine if hormones that regulate the volume and excretion of osmotic particles, sodium, and potassium in urine are altered in this environment.

**TECHNICAL APPROACH:** There will be 4 subjects, all male professional saturation divers. We will collect all urine and 11 blood samples each. The dive schedule will include 2 days pre-dive, 7 days at 450M, 4 days decompression and 4 days at 360M, 4 days decompression and two days decompression to 265M then 12 days decompression to sea level and 2 days post control. The study will begin September 30, 1989 and end November 8, 1989.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

None to date.

\*Exempt from committee protocol. (Multicenter study, we only run assays, procedures done at collaborating centers).



### Detail Summary Sheet

Prot No: 56A89	Status: Ongoing
TITLE: Mechanism of Cold Induced Diuresis	
Principal Investigator: Margaret S. Dice	
Associate Investigators: John R. Claybaugh, Ph.D.; Aileen K. Sato; Wayne M. Ichimura; CPT Beau J. Freund, MS	
Department/Section: Clinical Investigation/Physiology Section	
Key Words: cold diuresis;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: This study will attempt to clarify the hormonal determinants of cold diuresis. Specifically, the study will test the "Gauer-Henry hypothesis" whereby central blood volume expansion is proposed to increase water and sodium excretion. In addition experiments will be conducted to evaluate the role of the "Gauer-Henry" hypothesis in the onset and continuance of the cold diuresis.

TECHNICAL APPROACH: To evaluate the diuretic response of conscious rats to low ambient temperatures - blood pressure, relevant blood and urinary hormones, and urine flows will be measured via indwelling catheters. Bilateral cervical vagotomy will be performed to determine the contribution of cardiac low pressure receptors to the diuresis.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

To date the hormones aldosterone, atrial natriuretic peptide and vasopressin have been evaluated.

Detail Summary Sheet

Prot No: 28A87*	Status: Terminated
TITLE: Mechanism of Cold Induced Diuresis: a Pilot Protocol	
Principal Investigator: Margaret S. Dice, Biological Laboratory Technician	
Associate Investigators: John R. Claybaugh, Ph.D.; Aileen K. Sato; CPT Beau J. Freund, MS	
Department/Section: Clinical Investigation/Physiology	
Key Words: cold diuresis;	
Funding: FY 88: \$5,813. FY 89: \$16,260.	Periodic Review Date: Sep 89
Gifts: *NIH#HL28542	Decision: Terminate

OBJECTIVE: This is a pilot protocol to develop the rat as a model for studying hormonal determinants of cold diuresis.

TECHNICAL APPROACH: To evaluate the diuretic response of conscious rats to low ambient temperatures - blood pressure, relevant blood and urinary hormones, and urine flows will be measured via indwelling catheters. Consequently, the development of methods for surgically implanting and maintaining bladder, and femoral arterial and venous catheters is the primary technical focus of this pilot.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Nineteen animals have been surgerized to date. Surgical implantation of catheters has progressed to a satisfactory stage of ease and rapidity. Problems of catheter destruction by the animal have also been overcome.

\*Superseded by TAMC Protocol No. 56A89.

### Detail Summary Sheet

Prot No: 4A88

Status: Ongoing

TITLE: Are the Natriuretic and Diuretic Actions of Atrial Natriuretic Factor Dopamine Dependent?

Principal Investigator: CPT Beau J. Freund, Ph.D., MSC

Associate Investigators: John R. Claybaugh, Ph.D.; MAJ Albert H. McCullen, VC,

Department/Section: Clinical Investigation/Biochemistry

Key Words: atrial natriuretic factor (ANF);

Funding: FY 88: \$877. FY 89: \$948. Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** 1) To document a diuresis and natriuresis during blood volume expansion with isotonic saline using the adult female goat as the experimental model. 2) To determine the response of atrial natriuretic factor (ANF) and dopamine to saline infusion. 3) To determine if a dopamine antagonist (Haloperidol or Domperidone) can blunt the infusion induced diuresis or natriuresis. 4) To determine any interactive effects of other fluid regulating hormones, i.e., plasma renin activity, aldosterone, or antidiuretic hormone.

**TECHNICAL APPROACH:** Ten female goats will be surgically prepared with an exteriorized carotid loop. Following recovery from surgery (minimum 2 weeks) experimental procedures to include bladder catheterization and blood volume expansion via saline infusion will occur both with and without dopamine blockade with halperidol. Renal and hormonal responses will be evaluated and statistically compared between the dopamine antagonist and control conditions.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date 5 goats have been prepared with an exteriorized carotid loop. Experimental procedures and hormonal assays are scheduled to occur over the next year.

### Detail Summary Sheet

Prot No: 39H88	Status: Ongoing
TITLE: Hormonal and Renal Responses to Exercise: Effects of Exercise Intensity	
Principal Investigator: CPT Beau J. Freund, MS	
Associate Investigators: Everett M. Shizuru, Graduate Student; John R. Claybaugh, Ph.D.; MAJ Thomas A. Perkins, MC; Glenn Hashiro, M.S.	
Department/Section: Clinical Investigation/Biochemistry	
Key Words: hormonal and renal responses;	
Funding: FY 88: \$1,512. FY 89: \$7,075.	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

OBJECTIVE: The purpose of this study will be to: 1) investigate the effects of exercise intensity on renal function; 2) determine the mechanisms responsible for the diuresis and natriuresis reported during low intensity exercise; and 3) to investigate the stimuli responsible for the release of atrial natriuretic peptide (ANP).

TECHNICAL APPROACH: Subjects: Eight to twelve healthy male subjects of varying fitness states and between the ages of 20 and 39 years will be recruited for this study. The methodology and experimental protocol will be explained in detail to all prospective subjects with written informed consent being obtained prior to data collection. In addition, all subjects will be informed that they may withdraw at any time from the study without ill will.

PROGRESS: No. of Subjects Enrolled - To Date: 8      Reporting Period: 8

All testing and data collection has been completed on the 8 subjects enrolled. Statistical analysis is currently being performed and manuscript is to be written over the next year.

Adverse Effects: No adverse effects occurred in any of the subjects.

### Detail Summary Sheet

Prot No: 57H89	Status: Ongoing
TITLE: Effect of Negative Pressure Breathing on Fluid and Electrolyte Balance in Human Subjects	
Principal Investigator: Roy A. Hebden, Ph.D. -	
Associate Investigators: John R. Claybaugh, Ph.D., CPT Beau Freund, MS; Glenn Hashiro, MS, Aileen K. Sato; Wayne Ichimura	
Department/Section: Clinical Investigation/Physiology Section	
Key Words: electrolyte;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	
Gifts: None	Decision: Continue

OBJECTIVE: The purpose of this study will be to examine the effect of negative pressure breathing on water and electrolyte homeostasis in human subjects.

TECHNICAL APPROACH: Eight to ten healthy male subjects of similar fitness states and between the ages of 20 to 35 years will be recruited for this study.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

This is a new study. To date, the co-investigators and I have tested out our various pieces of equipment using ourselves as subjects. Everything would appear to be in order, so we will soon be enrolling subjects.

### Detail Summary Sheet

Prot No: 6A88

Status: Completed

**TITLE:** The Ontogeny of Vasopressin Receptors in Vascular Smooth Muscle in the Rat\*

**Principal Investigator:** Linda K. Kullama, Ph.D.

**Associate Investigators:** John R. Claybaugh, Ph.D.; Kenneth T. Nakamura, MD;  
Dr. Venkataraman Balaraman, M.D.

**Department/Section:** Clinical Investigation/Physiology

**Key Words:** arginine vasopressin (AVP); vascular smooth muscle responses;

**Funding:** FY 88: \$6,161. FY 89: \$10,273.

**Periodic Review Date:** Sep 89

**Gifts:** Hawaii Heart

**Decision:** Completed

**OBJECTIVE:** The objective of this study is to investigate the ontogeny of vascular smooth muscle responses to arginine vasopressin (AVP) using aortic ring segments from fetal, newborn, and adult guinea pigs. We will examine the AVP-mediated vasoconstriction, vasodilation, and the effect of endothelium dependent relaxing factor (EDRF) on modifying changes in isometric force.

**TECHNICAL APPROACH:** Isolated vascular rings are mounted in organ bath and bathed in Krebs's solution aerated continuously with 95%O<sub>2</sub>, 5%CO<sub>2</sub>. Isometric contractile responses are studied by addition of cumulative doses of drugs mediating vasoconstriction. The responses are recorded using a Grass .03FT force displacement transducer attached to a Gould recording device. Thus dose response curves to the various vasoconstrictors are generated and differences compared using standard statistical tests.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

The results and conclusions of this study are contained in the publications resulting from this study (see below). Briefly, 1) receptor mediated contractility is present from 2 days of age for NEm AVP and AVT; 2) sensitivity to KCl and NE increases progressively during postnatal development while sensitivity to AVP and AVT slightly decreases in the first week of life and shows no progressive age related increase by 12 weeks; 3) AVP and AVT mediate contraction via a similar V<sub>1</sub> receptor.

**ABSTRACTS:** 1. Kullama LK, Balaraman V, Claybaugh JR and Nakamura KT. Comparative Ontogeny of Arginine Vasopressin (AVP), Arginine Vasotocin (AVT) and Norepinephrine (NE) Mediated Contraction in Rat Thoracic Aorta. The FASEB Journal. 3(3): A1024, 1989. 2. LK Kullama, V Balaraman, JR Claybaugh and KT Nakamura. Comparative Ontogeny of Vasopressin, Vasotocin and Norepinephrine Mediated Contraction in Rat Thoracic Aorta. Pediatric Research. 25(4): 69A, 1989.

**PRESENTATIONS** FASEB meetings, March 19-23, 1989; New Orleans, LA (poster).

**PUBLICATIONS:** Kullama LK, Balaraman V, Claybaugh JR, Ichimura WM and Nakamura KT. Ontogeny of Vasoconstrictor Neurohypophyseal Hormone Function in Rats. American Journal of Physiology (in press).

## Detail Summary Sheet

Prot No: 38A88

Status: Ongoing

**TITLE:** The Ontogeny of cGMP Mediated Relaxation in Smooth Muscle (e.g. aorta, pulmonary artery, trachea etc.,) of Developing Fetal, Newborn and Adult Guinea Pigs and Rats

**Principal Investigator:** Linda K. Kullama, Ph.D.; John R. Claybaugh, Ph.D.

**Associate Investigators:** Dr. Venkataraman Balaraman, M.D.;

Dr. Kenneth T. Nakamura, M.D.;

**Department/Section:** Clinical Investigation/Physiology

**Key Words:** ontogeny;

**Funding:** FY 88: \$6,128. FY 89: \$21,164. **Periodic Review Date:** Sep 89

**Gifts:** Grant\*

**Decision:** Continue

**OBJECTIVE:** The objective of this study is to determine the ontogeny of cGMP mediated relaxation in smooth muscle (isolated vascular rings, tracheal rings etc.,) of developing fetal, newborn and adult guinea pigs and newborn and adult rats. We will use three different classes of pharmacological agents which stimulate cGMP by different mechanisms, viz., directly at the level of smooth muscle, receptor mediated release and endothelium dependent relaxing factor (EDRF) mediated release.

**TECHNICAL APPROACH:** Isolated smooth muscle structures (vascular rings, tracheal rings) are mounted in isolated organ bath and bathed in Kreb's solution aerated continuously with 95%O<sub>2</sub>, 5%CO<sub>2</sub>. Isometric relaxation responses are studied by addition of cumulative doses of drugs mediating relaxation after the tissue is precontracted with a known constricting agent. The responses are recorded using a Grass .03FT force displacement transducer attached to a Gould recording device. Thus dose response curves to the various relaxing agents are generated and differences compared using standard statistical tests.

**PROGRESS:** No. of Subjects Enrolled - To Date : NA **Reporting Period:** NA  
To date we have studied the relaxation responses to sodium nitroprusside (SNP) and Atriopeptin III (APIII), stimulators of soluble and particulate guanylate cyclase, respectively. We have observed that there is a progressive increase in the relaxation mediated by SNP with age while responses mediated by APIII appear unchanged. Furthermore, methylene blue, a selective inhibitor of soluble guanylate cyclase blocks SNP responses in an age dependent manner, though incompletely, while it does not affect responses mediated by APIII. These studies have been done so far only in the thoracic aorta of the guinea pig. At present, further experiments to study the relaxation responses mediated by acetylcholine and A23187, stimulators of EDRF which in turn stimulates soluble guanylate cyclase are being planned. We further plan to study these responses in pulmonary arteries. **ABSTRACTS:** 1. Balaraman V, Kullama LK, Easa D, Robillard JE and Nakamura KT. Ontogeny of Sodium Nitroprusside and Atriopeptin III relaxation in aorta of guinea pigs. Pediatric Research 25(4):64A, 1989. **PRESENTATIONS:** 1. Society for Pediatric Research meetings, May 1-4, 1989. Washington D.C. (Platform presentation) 2. District VIII meeting of the American Academy of Pediatrics, Section of Perinatal Medicine, May 25-27, 1989. Anchorage, AK. (poster) Manuscript submitted for publication.

\*Research Corporation of the University of Hawaii Leahi Trust

### Detail Summary Sheet

Prot No: 44A88	Status: Completed
TITLE: Pilot Study: Investigation of Transplanted Tumor Cell Lines in Mice: Establishment of Cancer Models at Tripler AMC to Support Research Protocols in Pathology, Surgery, and Medicine	
Principal Investigator: COL Kay Alvin Kyser, MC	
Associate Investigators: LTC Y-T. Margaret Lee, MC; CPT Kraig S. Lerud, MC; Dan Brooks, MT; Cindy Ollinger; SGT Anne Brady	
Department/Section: Clinical Investigation	
Key Words: tumor cell lines;	
Funding: FY 88: \$2,425. FY 89: \$5,150.	Periodic Review Date: Sep 89
Gifts: None	Decision: Completed

**OBJECTIVE:** To establish experimental cancer models at Tripler to support training and research on naturally occurring and man-made antitumor substances.

**TECHNICAL APPROACH:** Transfer of technology from Letterman AMC to establish mouse tumor colony. Traditional cancer cell line transfer. Estrogen receptor quantification using computer enhanced microscopy.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Lung, breast and malignant melanoma cancer cell lines have been successfully moved from Letterman AMC. Tumor tissues have been collected for freeze-back.



### Detail Summary Sheet

Prot No: 27A89	Status: Ongoing
TITLE: The Prevalence of Hantavirus and Hantavirus Antibody in Rats on Oahu	
Principal Investigator: MAJ Albert H. McCullen, VC	
Associate Investigators: MAJ Michael J. Langford, VC	
Department/Section: Clinical Investigation/Veterinary Service	
Key Words: Hantavirus Antibody	
Funding: FY 88: NA	FY 89: \$3,309.
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** The objective of this proposed study is to elucidate the ecology of Hantavirus in both free running and laboratory rats on Oahu. The general approach to this problem will be to conduct a survey of laboratory and free running wild rats on Oahu to establish the presence of Hantavirus sp. and to determine its distribution. Seropositive rats will be examined to detect viral antigen in tissues and an attempt will be made to isolate the virus from antigen positive lung tissues. If isolation is successful the virus will be characterized biologically, immunologically, and antigenically.

**TECHNICAL APPROACH:** Blood samples will be obtained from laboratory rat and wild rat populations on the island of Oahu to screen for Hantavirus antibody. If animals have positive antibody titers to the virus, isolation and characterization will be attempted.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

To date antibodies to the Hantavirus have been detected in laboratory rats and wild rats. Virus isolation and characterization remain to be done.

### Detail Summary Sheet

Prot No: 58A89

Status: Ongoing

**TITLE:** The Ontogeny of "Cyclic Guanosine Monophosphate (cGMP) Dependent" and "cGMP Independent" Relaxation Mediated by Sodium Nitroprusside (SNP) and Atrial Natriuretic Factor (ANF) in the Thoracic Aorta of Guinea Pigs

**Principal Investigator:** Kenneth T. Nakamura, MD

**Associate Investigators:** Venkataraman Balaraman, MD; Linda K. Kullama, Ph.D.;  
Aileen K. Sato; Naomi Fujiwara;  
John R. Claybaugh, Ph.D; MAJ Edward Stevens, MC;  
CPT Bruce Pichoff, MC

**Department/Section:** Department of Clinical Investigation

**Key Words:** Cyclic Guanosine Monophosphate (cGMP)

**Funding:** FY 88: NA

FY 89: NA

**Periodic Review Date:** Sep 89

**Gifts:** Grant\*

**Decision:** Continue

**OBJECTIVE:** This proposed study is designed to define the ontogeny of "cGMP dependent" and "cGMP independent" relaxation in the thoracic aorta of guinea pigs mediated by SNP and ANF. Aortae from fetal, newborn and adult guinea pigs will be studied.

**TECHNICAL APPROACH:** Relaxation responses will be measured employing the isolated vessel technique measuring isometric force. cGMP will be extracted and assayed by RIA employing a commercially available kit (New England Nuclear). Protein content will be assayed according to the technique described by Lowrey.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Preliminary experiments have just begun. Approval for this project was granted one month ago.

\*Research Corporation of the University of Hawaii Leahi Trust

## Detail Summary Sheet

Prot No: 11H89\*

Status: Completed

**TITLE:** A Quality Assurance Study to Compare Two Treatment Modalities for Mandibular Fractures - An Analysis of Lost Duty Time and Hospitalization Costs to the Military

**Principal Investigator:** LTC Durwood E. Bach, DC

**Associate Investigators:** MAJ Gregory W. Boice, DC; MAJ Jeffery Dootson, DC

**Department/Section:** Dental Activity/oral/maxillary surgery

**Key Words:** maxillomandibular fixation;

**Funding:** FY 88: NA

FY 89: NA

**Periodic Review Date:** Sep 89

**Gifts:** None

**Decision:** Completed

**OBJECTIVE:** To analyze two different modalities of treatment for mandibular fractures: 1) Maxillomandibular fixation. 2) Rigid internal fixation (bone plating) without maxillomandibular fixation. To make comparison between these treatment modalities for length of hospitalization, hospitalization costs to the military, and lost duty time.

**TECHNICAL APPROACH:** Twenty Hospital patient records with mandible fractures treated with IMF were reviewed. Fifteen consecutive Active Duty patients were treated with open reduction and rigid fixation. These patients were returned to duty when determined fit for discharge from the hospital. Patients were issued food blenderizers if none was available to them. In the IMF treated group (I) the mean length of hospitalization was 44 days. For the rigid fixation group (II) 10.26 days. Lost duty time in group I was 36.44 days for group II 12.26 days. Meantime from injury to return to full duty in Group I was 50.17 days in group II was 26.06 days. Comparison of body weights at intervals revealed a similar pattern of weight loss or nutritional maintenance in both groups. There was no significant surgical or post operative complications associated with the rigid fixation group. Results indicate that, when appropriate, rigid fixation of mandible fractures markedly reduces the need for IMF and permits expeditious return to original duty assignment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 15    Reporting Period: 15

Data collection completed. Results will be presented at the AMSUS annual meeting in San Diego, CA, Nov. 1989.

### Detail Summary Sheet

Prot No: 12A89	Status: Ongoing
TITLE: Evaluation of a Composite Graft (Porous Particulate Hydroxyapatite-Particulate Marrow Cancellous Bone) for Onlay Augmentation of the Atrophied Alveolar Ridge with Simultaneous Placement of Endosseous Implants in Goats	
Principal Investigator: LTC Durwood E. Bach, DC	
Associate Investigators: COL Ricney F. Newhouse, DC; MAJ Gregory Boice, DC; MAJ Steven Perkins, DC; COL Jeffrey O. Hollinger, DC	
Department/Section: Dentistry/Oral Surgery	
Key Words: endosseous implants;	
Funding: FY 88: NA	FY 89: NA
Gifts: Pending USUHS	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To evaluate a composite graft system for augmentation of the atrophied alveolar ridge with simultaneous placement of 2 endosseous implant systems. Clinical evaluation to assess the degree of stability of the implant. Clinical and radiographic assessment to determine the degree of bone graft maintenance or resorption postoperatively. Histologic and histomorphometric analysis to quantitate osseointegration of the dental implants within the matrix of the graft.

**TECHNICAL APPROACH:** Each animal will have an augmentation and simultaneous implant placement on the right and left side of the maxilla and the mandible. There will be 4 surgical/experimental sites per animal. One side of the mandible/maxilla will be augmented with an autogenous particulate marrow graft and the opposite side will be augmented with a composite graft of 50% hydroxyapatite and 50% autogenous particulate marrow. The sites will be randomized.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Apparently protocol has been approved by HSC and forwarded through channels to Henry Jackson Foundation.

### Detail Summary Sheet

Prot No: 48A89	Status: Ongoing
TITLE: Microsurgery Training for Oral Maxillofacial Surgery Residents Using Rat Nerves and Vessels	
Principal Investigator: LTC Durwood E. Bach, DC	
Associate Investigators: COL Ricney Newhouse, DC: MAJ Gregory Boice, DC: MAJ Steven Perkins, DC: MAJ Michael Werner, DC: LTC Charles Ringold, DC	
Department/Section: Dental Activity/Oral Maxillofacial Surgery Service	
Key Words: oral maxillofacial;	
Funding: FY 88: NA	FY 89: \$5,261.
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To train residents in the techniques of epineural and fascicular nerve repair for nerves approximately 1mm in diameter. To train residents in the repair of arteries and veins approximately 1mm in diameter.

**TECHNICAL APPROACH:** A 2 day laboratory course was held on the 8, 9 August 1989 at Clinical Investigation. Tracheostomy, and sciatic nerve co-aptations were performed on rats in the lab.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA  
Eight rats were utilized for the course.

### Detail Summary Sheet

Prot No: 9H88	Status: Ongoing
TITLE: A Comparison of Complete Maxillary Denture Retention Before and After Magnetic Retention is Obtained Utilizing Osseointegrated Implants	
Principal Investigator: MAJ Gregory W. Boice, DC	
Associate Investigators:	
Department/Section: Dental Activity	
Key Words: osseointegrated implants;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Continue
Gifts: None	

**OBJECTIVE:** To measure the in vivo retention that is added to complete maxillary dentures by using rare earth magnets in conjunction with osseointegrated implants.

**TECHNICAL APPROACH:** Patients were selected on the basis of having an edentulous maxillary ridge and a suitable maxillary denture. A stainless bar was fixed to the palatal portion of the denture and reinserted into the patients' mouth. Using a Chattillon push-pull gauge, the patients' denture was pulled down and the force needed to break the seal was recorded. After those measurements were taken, 2 Interpore IMZ Titanium Endosseous implants were placed, 1 each at the maxillary canine area. The implants were allowed four months to osseointegrate then were uncovered and keepers were attached to the implants. Then 2 Jackson regular rare-earth magnets were placed in the patients' dentures in such away to achieve contact with the keepers when the dentures were fully seated. Pull out measurements were done after magnetic augmentation in the same way as before.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

During the follow-up year for this study several problems have occurred.

- 1) When the patients are wearing their magnetically augmented denture, the intermobile element in the IMZ implant are coming unscrewed. This problem has necessitated changing from teflon IME's to titanium IME's on four patients.
- 2) An additional four implants have been lost due to loading of the implants. One of the lost implants was on a patient who lost an implant at the uncovering appointment. Failed to integrate. This necessitated "sleeping" the remaining implants on these patients. One year follow-up radiographs and recall appointments are being done on all patients at this time.

### Detail Summary Sheet

Prot No: 64H88	Status: Ongoing
TITLE: A Comparison of Amitriptyline vs. Trazodone vs. Placebo as Adjuvants to Opiate Analgesics in the Management of Pain in Cancer Patients	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators:	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: amitriptyline; trazodone;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	
Gifts: Amitriptyline, Trazodone & Placebo Tablets	Decision: Continue

**OBJECTIVE:** a) Compare the relative effectiveness of amitriptyline and trazodone as adjuvants to opiate analgesics for the management of pain of malignant diseases. b) Quantify the "opiate sparing" effect of these two agents when used in conjunction with morphine sulfate. c) Evaluate the cost-efficiency/effectiveness of trazodone and amitriptyline, as adjuvants to opiate analgesics, in the treatment of pain associated with malignant disease.

**TECHNICAL APPROACH:** Patients agreeing to participate in the study will first be titrated to a dose of morphine sulfate that controls their pain satisfactorily. They will then be randomized to receive an additional drug (either 1. amitriptyline, 2. trazodone or 3. placebo). This will be double blind. When this additional drug is started, their morphine dose will be decreased by 25% and the patients will be monitored closely for their pain level. The patients will have constant access to additional morphine if and when they need it for breakthrough pain. The physician following the patient will be expected to adjust the regularly scheduled morphine based on any regularly occurring breakthrough pain. Patients will be followed for 60 days minimum.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Multi-institutional study to continue until study objective met. Status is ongoing.

### Detail Summary Sheet

Prot No: 19H84	Status: Ongoing
TITLE: Treatment of Graves' Ophthalmopathy with Cyclosporin	
Principal Investigator: COL Michael Bornemann, MC	
Associate Investigators:	
Department/Section: Medicine/Endocrine-Metabolic	
Key Words: Graves' ophthalmopathy;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' disease.

**TECHNICAL APPROACH:** This is a random crossover study comparing Cyclosporin therapy of Graves' ophthalmopathy versus the standard of current therapy, high-dose oral Prednisone. Because of potential toxicity, this is not a double-blind study. The drugs will be administered for three weeks each, and then the patient will be crossed over with clinical response measured by an ophthalmopathy index. There will be a pretherapy clinical assessment and the usual laboratory testing pre-, post-, and during therapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This Walter Reed collaborative protocol remains open anticipating any patients that might meet the study population criteria. No (new) subjects enrolled. Recommend on-going status. This is part of an Army-wide project with centralized support WRAMC.



### Detail Summary Sheet

Prot No: 31H86	Status: Terminated
TITLE: The Incidence of Clinically Relevant IgE-Hypersensitivity to Mold Spores in Hawaii	
Principal Investigator: MAJ Robert E. Bowen, MC	
Associate Investigators: MAJ William F. Long, MC	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: mold spores;	
Funding: FY 88: \$270. FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Terminate

OBJECTIVE: To determine whether or not the recently developed extracts of the mold spores, Myxomycetes, Basidiomycetes, and imperfect fungi represent clinically significant aeroallergens in Oahu.

TECHNICAL APPROACH: Two hundred adult patients will be skin-tested for common Hawaiian aeroallergens. In addition, nine spore extracts will be tested. Prick testing will be done first using a template on the back to insure uniformity. This will permit comparison with the three whole body imperfects. At the completion, the data will be collated.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Dr. Bowen ETS'd in Aug 88 and has not left any of his research protocol results. Presently, none of the other two allergists are familiar with his research project and cannot continue it. Request the study be terminated.

### Detail Summary Sheet

Prot No: 22H88	Status: Terminated
TITLE: "Double Blind, Multicenter; Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of HA-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock"	
Principal Investigator: COL Joel Brown, MC	
Associate Investigators: COL Jeffrey L. Berenberg, MC; MAJ Gerald R. Harrington, Jr., MC; MAJ Phillip P. Bruno, MC; MAJ Gary P. Jones, MC; MAJ Iris J. West, AN	
Department/Section: Medicine/Infectious Disease	
Key Words: gram-negative sepsis/gram-negative septic shock;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Terminate

**OBJECTIVE:** To test whether antibody against endotoxin core subfraction offers a safe treatment for septic shock.

**TECHNICAL APPROACH:** The multicenter study plans to enroll between 45 and 450 patients, with 50 patients at TAMC. Patients with sepsis or septic shock will be given a vial that contains either the antibody or a human serum albumen placebo. The code can be broken by rubbing a blackened area of the label with an alcohol pad.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol provided funds for a research nurse to be hired through CPOH. The paperwork for this position was submitted through TAMC and CPOH some time ago but the position has still not been filled. Funding for this protocol will not continue past December 1989. Chances of recruitment and significant progress in this study are now remote. I, therefore, prefer to terminate the study.

### Detail Summary Sheet

Prot No: 33H86	Status: Ongoing
TITLE: The Natural History of HTLV-III Infection and Disease in a United States Military Population	
Principal Investigator: COL Joel D. Brown, MC	
Associate Investigators: MAJ Robert Gates, MC	
Department/Section: Medicine/Infectious Disease Service	
Key Words: HTLV-III; AIDS; infection;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To assess the impact of HTLV-III infection on military readiness by defining the natural history of infection in the general military population and to form a study cohort upon which subsequent studies can be built.

**TECHNICAL APPROACH:** Personnel with confirmed HTLV-III infection who agree to participate will receive standard evaluation, counseling, and referral of contacts. Information will be centralized in a common data base. Serum and CSF samples will be stored at WRAIR for future testing. Follow-up studies will be performed every six months.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study enrolls volunteer HIV infected patients for epidemiologic and periodic clinical evaluation to determine the course of their disease over time. It is part of a multicenter protocol, and the study will continue for at least 1 more year. No investigational agents are involved therefore there were no adverse results. Two patients were dropped due to death from AIDS. Results: A total of 125 patients entered the study to date. Thirteen patients were enrolled in 1989. No publications were submitted by TAMC since it is a multi-centered study.

### Detail Summary Sheet

Prot No: 58H88	Status: Terminated
TITLE: BIG ANP in Salt and Water Retention States.	
Principal Investigator: CPT Steven E. Farrell, MC	
Associate Investigators: Nadine Wilson, Ph.D.; MAJ L. Harrison Hassell, MC; John Claybaugh, Ph.D.	
Department/Section: Medicine	
Key Words: big ANP;	
Funding: FY 88: NA	FY 89: 1,797.
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To demonstrate the prescence of Big ANP (a large peptide that crossreacts immunologically with antisera to regular (ANP) in disease states characterized by volume expansion; i.e., congestive heart failure, end-stage renal disease, and liver failure with cirrhoses and to quantify levels of Big ANP and Reg ANP in the serum of representative patients of these three disease states. Additionally, to search for presence of Big ANP in ascitic fluid of patients with liver failure (cirrhoses) and ascites.

**TECHNICAL APPROACH:** Obtain serum samples from approximately 8 patients of each disease state to be studied and 8 normal controls. (The serum will be obtained during routine admission blood draws and will consist of one 7cc purple top container per patient.) These disease groups are: 1-Congestive heart failure, 2-End-stage renal disease groups hemodialysis, and 3-Liver failure characterized by cirrhoses with ascites. Determine the concentration of Reg ANP and Big ANP in this sera by methods outlined by Dr. Wilson in the Department of Clinical Investigations. Obtain ascitic fluid by paracentesis of the eight subjects with liver failure and carry-out similar fluid analysis of ANP levels. (Ascitic fluid will be obtained during diagnostic or therapeutic paracentesis conducted for the clinical benefit of the patient, there will be no paracentesis conducted for the clinical benefit of the patient, there will be no paracentesis conducted solely for obtaining experimental specimens. The volume required will be approximately 10cc's). Correlate the Big ANP: Reg ANP ratio in the disease states and compare these with a group of "normal" subjects. Procedures to be performed on the subjects will consist of routine vascular blood draws on all subjects consist of and controls and abdominal paracentesis on the liver failure subjects alone.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Cancelled due to collaborator returning to Canada.

### Detail Summary Sheet

Prot No: 8H89	Status: Ongoing
TITLE: Evaluation of Anamnestic Response of Lymphocytes from Recipients of the Heptavax Vaccine who are HBsAb Negative	
Principal Investigator: CPT Albert G. Fedalei, MC	
Associate Investigators: MAJ Kenneth Sherman, MC, MAJ Merle S. Sprague, MC, MAJ Lawton A. Seal, MS	
Department/Section: Medicine	
Key Words: heptavax vaccine;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine if the lymphocytes from subjects who have previously received the Heptavax but are now HBsAb negative, are able to mount an anamnestic response to antigen challenge.

**TECHNICAL APPROACH:** Physicians and ancillary staff at Tripler Army Medical Center who received the Heptavax vaccine between 1981 and 1986 were identified by questionnaire. To date, 43 subjects met the initial criteria and were tested for antibody to the surface antigen of hepatitis B (HBsAb). Initial screen utilized an ELISA assay whose positive/negative cutoff corresponded to a cutoff level of 10 S.R.U. by RIA. Three subjects (approximately 7%) were found to be antibody negative. These were matched with HBsAb positive controls for age, sex, site of injection and time vaccine was administered. Peripheral blood mononuclear cells were isolated by differential Ficoll-Hypaque gradient centrifugation. The cells were washed and then suspended in culture medium in microtiter well plates. Stimulation was provided by use of PHA, Hepatax or Recombivax. One microgram of hepatitis B antigen was found to be optimal in preliminary studies. After stimulation, cells were labeled with tritiated thymidine to measure increased cell activity. The lymphocytes from all subjects showed significant stimulation in response to phytohemagglutinin (PHA).

**PROGRESS:** No. of Subjects Enrolled - To Date: 91      Reporting Period: 91

No adverse effects from the veni-puncture have been encountered to date. The lymphocytes from all subjects showed significant stimulation in response to phytohemagglutinin (PHA). HBsAb negative subjects all had a blast index of less than one. Two of the three antibody positive controls and a separate internal positive control had blast indexes between 1.43 and 3. The antibody positive individual with a blast index less than 1 was found to also have very low titer antibody on serial dilution.

### Detail Summary Sheet

Prot No: 541188	Status: Terminated
TITLE: A Prospective, Randomized, Double-Blind, Placebo Controlled Study of the Effects of 6 Months of Enalapril on Microalbuminuria in Patients with Insulin-Dependent Diabetes Mellitus	
Principal Investigator: CPT Rosemary Fitzpatrick, MC	
Associate Investigators: MAJ L. Harrison Hassell, MC; Dr. Craig Holland, M.D. CPT Robert A. Decker, MC	
Department/Section: Medicine	
Key Words: diabetes mellitus;	
Funding: FY 88: NA	FY 89: NA
Gifts: *HMJFAMM	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To see if Enalapril will decrease rate of microalbuminuria in patients with Insulin-Dependent Diabetes Mellitus.

**TECHNICAL APPROACH:** Randomized placebo controlled double-blind study with approximately 30 patients in control groups; 30 in treatment group. Control group receives placebo. Test group receives 5 mg Enalapril 4 times a day. Following patients- glucose control, GFR, timed basal urines for microalbuminuria. Compare test and control group.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

\*Study referred via Uniformed Services University of the Health Sciences (USUHS) to Henry M. Jackson Foundation (HMJF) for outside funding. During delays at USUHS study was completed and published by other authors.

### Detail Summary Sheet

Prot No: 55H88	Status: Ongoing
TITLE: A Direct Comparison Between the Cholesterol Lowering Effects of Psyllium Mucilloid and Bile Sequestering Agents	
Principal Investigator: CPT Gary D. Gazenski, MC	
Associate Investigators: CPT Steven E. Hill, MC; CPT Gary D. Gazenski, MC MAJ Suzanne Chang, RD	
Department/Section: Medicine	
Key Words: psyllium mucilloid;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To show that psyllium mucilloid is more efficacious than the bile sequestrant cholestyramine in reducing total serum cholesterol and low density lipoprotein.

**TECHNICAL APPROACH:** Two arm outcome study of approved medications.

**PROGRESS:** No. of Subjects Enrolled - To Date: 77      Reporting Period: 77

The protocol requires a total of 150 participants, of which 77 are currently enrolled in the project. Preliminary data does not tend to support the findings of the Psyllium Hydrophilic Mucilloid Study by Anderson, et. al. and could provide important clinical information concerning primary intervention for Hypercholesterolemia. Due to the numerous PCS moves this summer, the estimation date of completion has been changed to August 1990. CPT Timothy Pfanner, MC, Department of Medicine has assumed the position of Principal Investigator.

### Detail Summary Sheet

Prot No: 61188	Status: Terminated
TITLE: Prevention of Nosocomial Pneumonias and Stress Gastroduodenal Ulcers in Ventilated Patients (A Multi-Center Protocol)	
Principal Investigator: MAJ Ney Gore, MC (formerly: MAJ Gerald R. Harrington, MC)	
Associate Investigators: MAJ Mary Moser-Gautreaux, ANC; MAJ Sheila Bunton, ANC	
Department/Section: Medicine	
Key Words: nosocomial pneumonias;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** The objectives of the study are four-fold. 1) To determine if patients receiving adequate antiulcer prophylaxis and nonabsorbable antibiotics will have a decreased incidence of nosocomial pneumonia. 2) To determine if sucralfate may reduce the incidence of nosocomial pneumonia without increasing the incidence of gastroduodenal ulcer disease. 3) To determine if cimetidine and antacids have an effect on bacterial and fungal colonization of mechanically ventilated patients. 4) To determine if any of these regimens can decrease the incidence of nosocomial pneumonia in mechanically ventilated patients.

**TECHNICAL APPROACH:** The study will encompass all patients admitted to the Surgical and Medical Intensive Care Units. Any patient without pre-existing pneumonia requiring mechanical ventilation for longer than 24 hours and having no contraindication to ulcer prophylaxis will be asked to participate in the study. Patients receiving the oropharyngeal decontamination will also receive antacids and cimetidine while those in the sucralfate group will only receive sucralfate. Those receiving Famotidine will receive no other drugs. Patients receiving just cimetidine and antacids will be the standard therapy control arm. Patients undergoing surgical procedures may be on prophylactic or therapeutic antibiotics. This can alter the flora of the respiratory tree. This will be documented in the study as well as the type of procedures, underlying illness or the presence of ileus upon admission. The patients will be stratified for severity of illness using APACHE II scores. The end point of the study is the development of pneumonia, stress gastroduodenal ulcer disease as evidenced by clinically overt bleeding (bright red blood per NG, hematemesis, melena and/or decrease in hematocrit) or over 14 days or continuous mechanical ventilation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Withdrawal of TAMC MICU from this study as a primary investigator is no longer assigned to this center. I have no desire to pursue this study.



## Detail Summary Sheet

Prot No: 8L87	Status: Ongoing
TITLE: Noncompliant Behavior Among Hemodialysis Patients: Relationship to Disturbances of the Renin-Angiotensin-Aldosterone, Antidiuretic Hormone, and Atrial Natriuretic Hormone Axes	
Principal Investigator: MAJ L. Harrison Hassell, MC	
Associate Investigators: John R. Claybaugh, Ph.D.; Arnold Siemsen, MD; Jon Streltzer, MD	
Department/Section: Medicine/Nephrology	
Key Words: hemodialysis patients;	
Funding: FY 88: \$2,851. FY 89: \$323.	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** Designed to compare levels of plasma renin activity (PRA), aldosterone (PA), antidiuretic hormone (ADH), and human atrial natriuretic peptide (hANP) in compliant and noncompliant hemodialysis patients to those in both humans and experimental animals associated with stimulation of thirst and salt appetite. Abnormalities of these hormonal axes may provide inferential evidence of disturbances of thirst and salt appetite which may underlie noncompliant behavior.

**TECHNICAL APPROACH:** Hemodialysis patients have blood drawn before and after two consecutive hemodialysis treatments. Urine is collected in the interim to calculate residual renal function. Patients have been categorized according to pre-defined criteria of compliance as assessed by interhemodialytic weight gain. The study will evaluate relationships of normal abnormalities to compliant and noncompliant behavior.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

No adverse effects have occurred. Results of the study were presented to the 1989 FASEB meeting. Present plans include submission of manuscript. No further new patients will be enrolled in the study.

### Detail Summary Sheet

Prot No: 76H87	Status: Terminated
TITLE: Effect of Hemodialysis on Hearing Threshold	
Principal Investigator: MAJ L. Harrison Hassell, MC	
Associate Investigators: CPT Raymond J. Enzenauer, MC; MAJ Jeffrey W. Davies, MSC	
Department/Section: Medicine	
Key Words: hemodialysis; hearing threshold;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Terminate

**OBJECTIVE:** To assess the acute effect of a standard hemodialysis procedure and various modifications to include changing dialysate sodium concentration, replacement of solute loss with mannitol, and separating solute and fluid removal on middle and inner ear function.

**TECHNICAL APPROACH:** Lab studies (electrolytes, BUN, Cr, Osmolality Glucose, Calcium, Magnesium, Phosphorus), determination of hearing threshold, and tympanograms are performed before and after a "standard" or usually prescribed hemodialysis treatment. Phase II requires CIC approval; therefore, no patients have been enrolled.

**PROGRESS:** No. of Subjects Enrolled - To Date: 9      Reporting Period: 9

No adverse effects have occurred. Analysis of data from patients entering the study failed to demonstrate effects of HD on hearing threshold. Therefore, the study is terminated. Phase II studies will not be undertaken.

### Detail Summary Sheet

Prot	17H88	Status: Ongoing
TITLE: Impact of Clinical Laboratory Methodology on the Accurate Measurement of Serum Chloride and Calculated Bicarbonate from Arterial Blood Gases and the Clinical Approach to the Diagnosis of Acid-Base Disorders		
Principal Investigator: MAJ L. Harrison Hassell, MC		
Associate Investigators:		
Department/Section: Medicine		
Key Words: serum chloride;		
Funding: FY 88: NA	FY 89: NA	Periodic Review Date: Sep 89
Gifts: None		Decision: Continue

**OBJECTIVE:** a. To determine the effect of the clotted RBC mass on the accurate measurement of serum chloride and calculated bicarbonate from arterial blood gases b. To determine the effect of air exposure on the accurate measurement of serum chloride and calculated bicarbonate from arterial blood gases. c. To test the clinical maxim, "arterial blood gas values should be validated before being used in clinical decision making."

**TECHNICAL APPROACH:** Arterial blood is sampled and divided into a series of blood tubes designed to assess effects of various post-phlebotomy effects on the laboratory determination of the serum bicarbonate. This data is combined with arterial blood gas measurements to determine whether post-phlebotomy effects will alter the diagnosis of acid-base disorders.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

This study is laboratory intensive and requires extensive computer programming to account for all variable effects. However, the question is still valid and completion is planned.

### Detail Summary Sheet

Prot No: 43H89*	Status: Ongoing
TITLE: Clinical Utility of Post-Thoracentesis Chest Roentgenography	
Principal Investigator: CPT William D. Holland, MC	
Associate Investigators: CPT Oleh Hnativ, MC; MAJ John D. Olsen, MC	
Department/Section: Medicine	
Key Words: post-thoracentesis; roentgenography;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** The purpose of this study is to prospectively assess whether the routine use of post-thoracentesis chest roentgenography in asymptomatic patients without clinically apparent complications is warranted. This prospective study hopes to provide unbiased, well documented evidence needed to calculate an accurate negative predictive value for the parameters identified in our retrospective review.

**TECHNICAL APPROACH:** No alteration from basic standards of medical practice. Followup of pt's thoracentesis will involve reviewing thoracentesis form and reviewing CYR.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Due to delay in receiving standardized thoracentesis forms (received 14 Sept) project initiated 15-18 Sept 89. No subjects at present.

\* Exempt from committee protocol (retrospective study).

### Detail Summary Sheet

Prot No: 10H89	Status: Ongoing
TITLE: Double Blind Trial of Sucralfate in the Treatment of Minor Aphthous Stomatitis	
Principal Investigator: CPT James K. Howden, MC	
Associate Investigators:	
Department/Section: Medicine	
Key Words: sucralfate; aphthous stomatitis;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

OBJECTIVE: Recurrent aphthous stomatitis, commonly known as canker sores, is estimated to affect 20 percent of the general population. (1) Effective therapy of the common idiopathic aphthous ulcerative type is not available. Because of promising results in the therapy of chemotherapy associated oral mucositis, a therapeutic trial with sucralfate is proposed.

#### TECHNICAL APPROACH:

After being assessed through questionnaire, short physical exam and complete blood count, patients are randomly assigned, in blinded fashion, to either the treatment or placebo group. The patient's consent is obtained and he is given a prescription. The patient is instructed to begin therapy on the initiation of symptoms and to call the Internal Medicine Clinic to arrange follow up within one day. The patient is thereafter seen every two days for a total of ten days to assess for subjective and objective improvement.

PROGRESS: No. of Subjects Enrolled - To Date: 15      Reporting Period: 15

Presently the collection of data is on going.

### Detail Summary Sheet

Prot No: 27H88	Status: Ongoing
TITLE: A Treatment Protocol for the Use of Trimetrexate with Leucovorin Rescue for AIDS Patients with <u>Pneumocystis Carinii</u> Pneumonia and Serious Intolerance to Approved Therapies	
Principal Investigator: Dr. Arthur C. Johnson, M.D. Associate Investigators: COL Joel D. Brown, MC	
Department/Section: Medicine/Infectious Disease	
Key Words: Leucovorin; Pneumocystis Carinii pneumonia (PCP);	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

OBJECTIVE: To make available this treatment approach to our patients pending FDA approval. To add to existing information on the safety and efficacy of Trimetrexate with leucovorin rescue in AIDS patients with Pneumocystis Carinii pneumonia (PCP) who have no therapeutic alternatives because they have demonstrated serious (severe or life threatening) intolerance to both conventional therapies for PCP.

TECHNICAL APPROACH: Treatment protocol (national).

PROGRESS: No. of Subjects Enrolled - To Date: 1    Reporting Period: 1

Project is ongoing. No new additional patients have been enrolled. It is part of a multicenter protocol. Recent changes in the treatment and prophylaxis of Pneumocystis carinii pneumonia (PCP) have greatly reduced the incidence and recurrence of this disease. No new patients were treated in FY 89 therefore there were no adverse effects. Results: Accrual of subjects has been significantly less than initially anticipated. No publications were submitted by TAMC since this is a multi-center study.

Detail Summary Sheet

Prot No: 10H88	Status: Terminated
TITLE: Assessment of Nonspecific Decrease in Skin Test Reactivity and Late Phase Reactions During Immunotherapy	
Principal Investigator: MAJ Marcia L. Muggelberg, MC	
Associate Investigators:	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: immunotherapy;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Terminate

OBJECTIVE: To determine whether there is a nonspecific decrease in skin test reactivity to unrelated extracts during immunotherapy and to determine the effect of immunotherapy on the late response.

TECHNICAL APPROACH: Observational study of skin test changes during indicated immunologic treatment.

GRESS: No. of Subjects Enrolled - To Date: NA    Reporting Period: NA

Terminated. Never started in Hawaii. Similar study done by another investigator.

Detail Summary Sheet

Prot No: 11H88	Status: Ongoing
TITLE: Efficacy of Steroids in the Acute Treatment of Asthma: Are Duration of Symptoms Important?	
Principal Investigator: MAJ Marcia L. Muggelberg, MC	
Associate Investigators: MAJ T. R. Vaughan, MC	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: efficacy of steroids; asthma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

OBJECTIVE: To determine whether the efficacy of steroids for the treatment of asthma in the acute setting is related to the duration of the patients' symptoms for that episode of asthma.

TECHNICAL APPROACH: Prospective data collection; standard patient care.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA  
New Start.



### Detail Summary Sheet

Prot No: 12H88	Status: Ongoing
TITLE: Multicenter Clinical Evaluation of Penicillin Skin Testing Materials	
Principal Investigator: MAJ Marcia L. Muggelberg, MC	
Associate Investigators:	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: penicillin allergy;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

OBJECTIVE: 1) To determine whether there is a difference in the incidence of skin test positivity to the different skin testing reagents prepared by different methods in patients with a history of penicillin allergy as well as in subjects with no previous history of an adverse reaction to a penicillin-like drug. 2) To study the comparative potency, as determined by cutaneous endpoint titration skin testing, of reagents prepared by different methods in skin test positive patients. 3) To compare skin test reactivity to freshly reconstituted reagents with that produced by aged reagents.

TECHNICAL APPROACH: Test-arm trials.

PROGRESS: No. of Subjects Enrolled - To Date: 7    Reporting Period: 7

New start.

### Detail Summary Sheet

Prot No: 32H89	Status: Ongoing
TITLE: The Effect of Cancer Chemotherapy on the Reactivation of Chronic Hepatitis B Infection	
Principal Investigator: CPT Rickey C. Myhand, MC	
Associate Investigators: COL Jeffrey Berenberg, MC; COL Charles C. Jones, MC; MAJ Kenneth Sherman, MC; COL Joseph Woods, MC; LTC Bruce A. Cook, MC	
Department/Section: Medicine	
Key Words: chronic hepatitis B;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** Cases of reactivation of chronic hepatitis B infection with resultant acute hepatitis and death have been described in the literature. The changing status of hepatitis B infection in patients who receive cancer chemotherapy has not been evaluated in a prospective study. Specific questions to be addressed by this study are: 1) Does hepatitis B reactivation and subsequent liver damage occur frequently in chronic carriers who receive cancer chemotherapy for malignancy? 2) Should candidates for cancer chemotherapy be routinely screened for chronic hepatitis B infection? 3) Is there a morphologic/histopathologic distinction between chemotherapy induced hepatotoxicity and viral induced liver disease?

**TECHNICAL APPROACH:** Screen patients receiving or about to receive chemotherapy (screen for positive HBsAg). If positive, obtain consent to enter study. When consent is obtained, obtain baseline studies of HBsAg, Delta Ag and Ab, HBcAB (IgM, IgG), HBeAg, HBeAb, HB serum DNA probe, HAV Ab, SGOT, SGPT, GGT, Tibili, Alkaline Phosphatases, T-Helper/Suppressor ratio, cytotoxic T-cell. Liver biopsy (excluding pediatric patients) upon entrance of study and at the completion of chemotherapy regimen. Follow baseline studies monthly. Total number of patients required for study: 15-20  
Duration of study: 2 years.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Still screening prospective patients for HBsAg.

### Detail Summary Sheet

Prot No: 2H86	Status: Ongoing
TITLE: Systolic Hypertension in the Elderly Program	
Principal Investigator: CPT Howard J. Zimring, MC (formerly: COL Garold L. Paul, MC)	
Associate Investigators: Dr. Helen Petrovitch, M.D. (Principal Investigator in Hawaii for the national SHEP study)	
Department/Section: Medicine	
Key Words: hypertension;	
Funding: FY 88: NIH*	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To assess whether long-term administration of antihypertensive therapy to elderly subjects with isolated systolic hypertension reduces the combined incidence of fatal and nonfatal stroke.

TECHNICAL APPROACH: The study will be a double-blind, placebo-controlled, randomized clinical trial. Half of the participants will be given active intervention using a step-up treatment program. The other half will be randomly assigned to placebo.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA  
Study ongoing. No progress to report.

\* (Division of Heart, Lung and Blood)

### Detail Summary Sheet

Prot No: 40H89	Status: Ongoing
TITLE: A Blinded HIV Seroprevalence Survey Utilizing Cord Blood Specimens Routinely Collected for Neonatal RH Antibody Titer and Hematocrit Testing	
Principal Investigator: LTC Margaret M. Baird, RN, MS	
Associate Investigators: Dr. Patricia Nishimoto, Ph.D., RN	
Department/Section: Nursing	
Key Words: HIV seroprevalence;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To identify HIV Seroprevalence in childbearing women in Honolulu - as one of 30 metropolitan areas in an ongoing CDC study. The purpose is to define risk areas for targeting education for prevention and future resources for care and treatment.

**TECHNICAL APPROACH:** An additional take of cord blood will be obtained at the time of delivery to test for HIV Seroprevalence.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

To date, there are no subjects enrolled in the study. Materials (cord blood collection tubes, racks and labels) and demographic sheets (currently being printed) have been ordered. The study will not begin until these materials are all available. The expected date to begin, since the delay in obtaining equipment, is 1 October 1989.

### Detail Summary Sheet

Print No: 17H89	Status: Completed
TITLE: Metoclopramide's Effectiveness in Reducing Post-Operative Nausea and Vomiting When Administered Post-Operatively as Compared to Intra-Operative Administration	
Principal Investigator: CPT Douglas M. Baysinger, II, AN	
Associate Investigators: CPT Carl A. Cheramie, AN; CPT Paula M. Varney, AN	
Department/Section: Nursing/Anesthesiology Nursing Section	
Key Words: metoclopramide; nausea; vomiting; post-operative	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Completed

OBJECTIVE: The purpose of this project is to determine whether there is any difference in the antiemetic/antinausea properties of metoclopramide given intra-operatively as compared to its administration in the recovery room.

TECHNICAL APPROACH: The accessible population will be all adult female patients presenting for elective gynecological laparoscopy and D&C at TAMC. From this population a convenience sample of ASA I and ASA II category patients who meet the described criteria will be included in the study. A minimum of twenty-five patients will be in each group.

PROGRESS: No. of Subjects Enrolled - To Date: 50      Reporting Period: 50

Data collection has been completed. We are in the process of writing the project.

### Detail Summary Sheet

Prot No: 531189	Status: Ongoing
TITLE: The Effect of Therapeutic Massage on Patient's Back Pain after Cardiac Catheterization	
Principal Investigator: Lolita A. Ching, RN	
Associate Investigators:	
Department/Section: Nursing/Medical Intensive Care Unit	
Key Words: therapeutic massage;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

**OBJECTIVE:** To determine if therapeutic massage has an effect on the patient's back pain after cardiac catheterization. To determine if patients who receive therapeutic massage will decrease the rate of back pain as measured by the visual analogue scale than the patients who do not receive therapeutic massage.

**TECHNICAL APPROACH:** The study will be a non-equivalent pretest posttest contro quasiexperimental design. A convenience sample of 30 subjects with 15 subjects in each group will be given a visual analogue scale to rate the pain intensity before and after the intervention.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

At this point, patient who received therapeutic massage has a significant reduction of back pain clinically as compared to the patient who repositioned on the right side. Further data collection is needed (for) to check statistical significance.

### Detail Summary Sheet

Prot No: 37H85

Status: Terminated

TITLE: Nutritional Support of the Hospitalized Patient: A Comparison Between Continuous and Intermittent Administration of Enteral Tube Feedings

Principal Investigator: CPT Theresa A. Taylor, AN  
Associate Investigators:

Department/Section: Nursing

Key Words: enteral tube feeding;

Funding: FY 88: NA FY 89: NA  
Gifts: None

Periodic Review Date: Sep 89  
Decision: Terminate

**OBJECTIVE:** To ascertain which mode of tube feeding administration, intermittent or continuous, is optimal for the hospitalized patient in regard to maximizing the benefits of nutritional support and minimizing adverse reactions.

**TECHNICAL APPROACH:** Subjects for the study are selected from a surgical ward population of patients and must meet the criteria of being unable or unwilling to consume caloric needs by p.o. intake alone. Patients from both the otorhinolaryngology and neurosurgical services are considered and entered into the study if enteral tube feeding nutritional support is indicated, and patients are randomly assigned to either mode of administration. After one week of the initial mode of administration, the patient is changed to the alternate mode for another week. Data is collected by nursing staff responsible for the care of the patient per intake and output worksheets and study-specific data sheets. If patients demonstrate a desire to eat, they must be eliminated from the study.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Study terminated due to PCS of investigator, CPT Theresa Taylor in June 1988.

### Detail Summary Sheet

Prot No: 32H88	Status: Ongoing
TITLE: Vasoconstriction and Anesthesia for Intranasal Surgery: Is Cocaine Really Necessary?	
Principal Investigator: CPT Terry C. Wicks, ANC	
Associate Investigators: CPT Timothy A. Newcomer, AN MAJ Marc A. Paradis, MC	
Department/Section: Nursing/Anesthesiology Nursing Section	
Key Words: intranasal surgery; vasoconstriction;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To examine whether or not 4% lidocaine with 0.002% oxymetazoline can provide anesthesia and vasoconstriction comparable to 4% cocaine when applied topically. Is ephinephrine in a concentration of 1:200,000 as effective in reducing blood in the operative field as epinephrine 1:50,000 when infiltrated into nasal tissue?

**TECHNICAL APPROACH:** Double blind, treatment arm trial of standard, in use procedures.

**PROGRESS:** No. of Subjects Enrolled - To Date: 60      Reporting Period: 60

Since last report an additional 60 subjects have been studied. Thus far all subjects in this study have received adequate vasoconstriction and anesthesia. Two subjects were dropped from the study because of failure to follow the study protocol. One patient experienced a transient increase in heart rate and blood pressure and the code was broken as a safety precaution. The patient's vital signs normalized within a few minutes and he suffered no sequela as a result of participation in the study. Data collection for this study should be complete by August 1990.



## Detail Summary Sheet

Prot No: 14H88

Status: Terminated

TITLE: Use of the PGE2 Vaginal Suppository in Cervical Ripening and/or Labor Induction

Principal Investigator: CPT Stephen J. Andrews, MC

Associate Investigators: MAJ Robert W. Smith, MC;  
MAJ Jerome N. Kopelman, MC;  
COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: PGE2 vaginal suppository;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Terminate

**OBJECTIVE:** Establish the efficacy and safety for the term parturient and her fetus of the PGE2 vaginal suppository (3.0 mg) as an inducing and ripening agent for unripe cervixes.

**TECHNICAL APPROACH:** Patient with medical or obstetric indication for induction with unripe cervix will be randomized to either Pitocin induction vs PGE2 suppository. Resident and staff assigned to Labor and Delivery will follow patient according to protocol and neonate will be followed in newborn nursery according to protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

The study has been terminated for the following reasons:

- 1) The exclusion criteria were too rigid to permit the acquisition of data in a timely fashion.
- 2) The Division of Maternal-Fetal Medicine preferred to emphasize the use of PGE2 in a gel vehicle rather than the suppository vehicle and to proceed on the basis of a use protocol. Continuance of the study protocol, encumbered by very rigid exclusion criteria would only serve to split the effort of this department relative to the use of PGE2 in cervical ripening. The number of patients enrolled in the study was far too few (three) to allow any statement of accomplishment.

Detail Summary Sheet

Prot No: 47H88	Status: Ongoing
TITLE: Uterine and Umbilical Artery Blood Flow Change in Cesarean Section Under Subarachnoid Block	
Principal Investigator: MAJ Joseph P. Bruner, MC	
Associate Investigators: COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: subarachnoid blood;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** The purpose of the present study is to measure changes in uterine and umbilical artery blood flow velocity waveforms that occur during administration of subarachnoid block in doses adequate to perform delivery by cesarean section. Conduction anesthesia is commonly employed for obstetric pain relief. The anesthetic agents used can be sympatholytic, however, and thus effect resting vascular tone.

**TECHNICAL APPROACH:** All patients admitted to the labor floor for scheduled repeat Cesarean section under subarachnoid block will be eligible to participate in the study. Data descriptive of the patient population and anesthesia procedure will be collected. Subarachnoid block will be administered according to established protocol and observing recognized guidelines of intravenous access, fluid volume preload, maintenance of physiologic blood pressure, and left uterine displacement. Baseline uterine and umbilical artery flow velocity waveforms will be recorded after the fluid load, and again after an anesthetic level of T<sub>10</sub> to L<sub>4</sub> has been obtained.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 4  
Study ongoing.

## Detail Summary Sheet

Prot No: 48H88

Status: Ongoing

TITLE: Continuous Instantaneous Assessment of the Adequacy of Fetal Cerebrovascular Perfusion by Means of Transvaginal Continuous Wave Doppler Ultrasonography of the Fetal Anterior Cerebral Arteries Through the Anterior Fontanelle

Principal Investigator: MAJ Joseph P. Bruner, MC

Associate Investigators: COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: fetal anterior cerebral arteries;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

OBJECTIVE: The purpose of the present study is: (1) to determine the feasibility of continuous transvaginal Doppler ultrasonography of the fetal anterior cerebral arteries during labor and delivery; (2) to determine the best means of fetal anterior cerebral artery waveform analysis for clinical applications; (3) to correlate recorded flow velocity waveforms with methods of intrapartum fetal surveillance currently in use; (4) to assess the desirability of developing a prototype for an integrated Intrapartum Fetal Surveillance Monitor.

TECHNICAL APPROACH: After cerebral artery flow velocity wave forms measured manually during labor, delivery and the neonatal period and compared to known standards.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Study ongoing.

### Detail Summary Sheet

Prot No: 31189	Status: Ongoing
TITLE: Chorionic Villous Sampling in a Military Population	
Principal Investigator: MAJ Joseph P. Bruner, MC	
Associate Investigators: MAJ Jerome N. Kopelman, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: (CVS);	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Nov 88 Decision: Continue

**OBJECTIVE:** The purposes of this project are: (1) to compare the efficiency of ultrasonically directed transabdominal needle biopsy of chorionic villi to midtrimester genetic amniocentesis; (2) to compare the efficiency of obtaining chromosome preparations which are suitable for clinical laboratory testing from these samples.

**TECHNICAL APPROACH:** Patients with requirement for early prenatal diagnosis or need for large tissue sample candidates for CVS. Specimens obtained under ultrasound guidance and processed at Vivigen, Santa Fe, NM. Details of clinical course, specimen collection, antepartum care, delivery and neonatal examination collected and compared to midtrimester amniocentesis and early amniocentesis. Data collection coordinated with tissue lab at Vivigen.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5      Reporting Period: 5

All studies performed in first and second trimesters for prenatal diagnosis in living fetuses. All karyotypes normal. All fetuses live born at term. All neonates normal. No complications noted.

### Detail Summary Sheet

Prot No: 29H89	Status: Ongoing
TITLE: Development of a Standard Technique of Insonation of the Umbilical Artery with Continuous Wave Doppler Ultrasound	
Principal Investigator: MAJ Joseph P. Bruner, MC	
Associate Investigators: CPT Thomas J. Luetkehans, MC, CPT Beau J. Freund, MS CPT Gregory Logsdon, MC	
Department/Section: Obstetrics and Gynecology/Perinatology Service	
Key Words: doppler ultrasonography;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: The purpose of the present study is to determine a standard technique for measuring the umbilical artery during pregnancy with continuous wave Doppler ultrasound.

TECHNICAL APPROACH: FVM SID ratio of placental cord insertion site, midcord segment, and abdominal cord insertion site measured with duplex Doppler in radiology. Examination follows immediately in OB/GYN clinic with continuous wave Doppler machine, measuring easiest site, next easiest site, etc, until all 4 quadrants sampled. Analysis of correlation will follow.

PROGRESS: No. of Subjects Enrolled - To Date: 4      Reporting Period: 4  
Study ongoing.

### Detail Summary Sheet

Prot No: 30H89	Status: Terminated
TITLE: Doppler Ultrasound Examination of Maternal Uterine and Fetoplacental Vessels in Complicated Pregnancies	
Principal Investigator: MAJ Joseph P. Bruner, MC	
Associate Investigators: CPT Thomas J. Luetkehans, MC	
Department/Section: Obstetrics and Gynecology/Perinatology Service	
Key Words: doppler ultrasonography;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Terminate
Gifts: None	

**OBJECTIVE:** The purpose of the present study is to determine the efficacy of Doppler Ultrasonography of maternal and fetal vessels in the diagnosis and management of complicated pregnancies.

**TECHNICAL APPROACH:** Patients selected for the study will have a pregnancy complication, the diagnosis or management of which may benefit from Doppler studies of blood flow. The equipment and techniques of study have been carefully described previously. Examination results will be placed in the inpatient/outpatient record by the examining physician, along with an interpretation of test results. Evidence of adequate patient counseling by a staff perinatologist will be placed in the medical record. Demographic variables and parameters of perinatal outcome will be recorded for possible future analysis.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA  
Terminated. Protocol now used as SOP. Data not being collected.

### Detail Summary Sheet

Prot No: 33H88	Status: Completed
TITLE: Cefamandol Irrigation vs. Parenteral Cefadyl or Cefoxitin Prophylaxis and the Relationship of Bladder Flap Closure to the Incidence of Postpartum Endometritis	
Principal Investigator: CPT John W. Byron, MC	
Associate Investigators: CPT Michael D. Bork, MC; MAJ Jerome N. Kopelman, MC; COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: cefamandol irrigation;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Completed

**OBJECTIVE:** To determine the effect of bladder flap closure on the incidence of postpartum endometritis as well as the associated complications e.g., abscess formation. Simultaneously, the use of prophylactic antibiotics in our patient population will be examined in order to determine the most effective regimen. Cefamandol irrigation will be compared with Cefoxitin and Cefadyl parenteral antibiotics.

**TECHNICAL APPROACH:** All patients in Labor and Delivery scheduled for C-section are considered as candidates for random number blindly for and assigned respectively. Bladder flap (open or closed) will be assigned at random according to protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 300      Reporting Period: 300

Study was performed from September 1988 through June 1989 with enrollment of over 250 patients. Research results have yet to be analyzed.

### Detail Summary Sheet

Prot No: 34H88	Status: Ongoing
TITLE: A Prospective Evaluation of Laparoscopic Techniques Verres Needle Insufflation vs. Direct Trocar Insertion	
Principal Investigator: CPT John W. Byron, MC	
Associate Investigators: CPT Glenn R. Markenson, MC; MAJ Milo L. Hibbert, MC; COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: Laparoscopic techniques;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** To compare the efficiency and safety between two laparoscopic techniques in a prospective manner. Determine if direct insertion technique offers benefits of decreased time of surgery and reduction in amount of pneumoperitonium required.

**TECHNICAL APPROACH:** Patients for the proposed study will come from those undergoing laparoscopic procedures through any of the gynecologic teams: GYN Oncology Team, GYN Team, Family Planning or Infertility Service. Informed consent will be obtained prior to the procedure. Patients will then be randomized into one of the two groups with the procedure to be performed located on the surgeon data sheet. The data sheet will remain sealed until immediately prior to surgery. A data sheet will be completed by the operating surgeon in conjunction with the anesthetist. Data sheets will then be collected by an author who will check them for accuracy and completeness.

**PROGRESS:** No. of Subjects Enrolled - To Date: 200 Reporting Period: 200

Study was performed from September 1988 through June 1989 with over 200 patients enrolled. Results to be analyzed at this point. May possibly extend enrollment if necessary with CPT Glenn R. Markenson/MAJ Milo L. Hibbert, MC continuing in my place, after I PCS this summer.



### Detail Summary Sheet

Prot No: 35H89	Status: Ongoing
TITLE: Effect of Local Infiltration Anesthesia of Abdominal Incisions on Post-Operative Pain Relief and the Requirement for Post-Operative Pain Medication	
Principal Investigator: CPT James W. Hubbard, MC	
Associate Investigators: LTC J. Benjamin Hall, MC; MAJ Joseph P. Bruner, MC;	
Department/Section: Obstetrics and Gynecology	
Key Words: Intra-operative infiltration;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To evaluate the effect of incisional infiltration of bupivacaine versus normal saline infiltration vs. no treatment upon subjective perception of post-operative pain and the requirement for pain medication in women undergoing cesarean section.

TECHNICAL APPROACH: Patients are matched for 1) No treatment. 2) Infiltration with normal saline or 3) Infiltration with 0.25% Marcaine. Performed following closure of rectus fascia and prior to skin closure.

PROGRESS: No. of Subjects Enrolled - To Date: 63      Reporting Period: 63

63 patients enrolled to date. No data compilation has occurred to date. To commence upon enrollment of 100 patients.

### Detail Summary Sheet

Prot No: 17H87	Status: Ongoing
TITLE: Comparison of Pregnancy Rates Using Oil-based and Water-based Contrast Medium in the Evaluation of Tubal Patency	
Principal Investigator: MAJ Gerard S. Letterie, MC	
Associate Investigators: COL Kunio Miyazawa, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: tubal patency;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine if the use of oil-based contrast medium in the evaluation of tubal patency enhances fertility when compared to water-based solutions.

**TECHNICAL APPROACH:** Sixty patients fulfilling the study criteria will be entered into one of two random study groups. Group I patients will have an oil-based contrast medium injected during the intra-operative tubal insufflation and a water based contrast medium will be used in an identical fashion on Group II patients. Effectiveness will be determined by the conception rates for the two groups at the end of a three month period.

**PROGRESS:** No. of Subjects Enrolled - To Date: 30      Reporting Period: 30

Thirty patients have been entered, fifteen into each of two groups (as described above). Six pregnancies in the oil-based group and one patient in the water-based group have been observed. This difference was statistically significant (Fisher's Exact Test). No adverse effects were noted. Preliminary manuscript is in preparation.

### Detail Summary Sheet

Prot No: 29H87 Status: Ongoing

TITLE: Evaluation of Missed Pills on the Effectiveness of Oral Contraception

Principal Investigator: MAJ Gerard S. Letterie, MC

Associate Investigators: LTC James Wilson, MC

Department/Section: Obstetrics and Gynecology

Key Words: oral contraception;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** To determine if missed pills in an oral contraceptive cycle result in the sequence of follicular maturation and eventual ovulation.

**TECHNICAL APPROACH:** Ten patients will be assigned to each group on a rotating basis for a total of 20 patients. The study population will consist of volunteers drawn from these patients referred to the Reproductive Endocrinology Service, Department of Obstetrics and Gynecology for tubal reanastomosis. The use of this specific population will enable a manipulation of an oral contraceptive regimen without the risk of pregnancy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8 Reporting Period: 8

Eight patients have been entered. Results are preliminary. Study will be continued until a full complement of patients has been achieved. No adverse effects have been noted. Study is ongoing.

## Detail Summary Sheet

Prot No: 4H89

Status: Ongoing

TITLE: A Prospective Evaluation of Serial Concentrations of Human Atrial Natriuretic Peptide (ANP), Plasma Renin Activity, and Aldosterone, in Normal Pregnancies, and Those at Risk for Preeclampsia

Principal Investigator: CPT Glenn R. Markenson, MC

Associate Investigators: MAJ Jerome Kopelman, MC; John Claybaugh, Ph.D.;  
CPT Beau J. Freund, MS; COL Kunio Miyazawa, MC

Department/Section: Obstetrics and Gynecology

Key Words: atrial natriuretic peptide (ANP);

Funding: FY 88: NA  
Gifts: None

FY 89: \$5,011.

Periodic Review Date: Sep 89  
Decision: Continue

OBJECTIVE: (1) To determine if ANP secretion is altered during pregnancy. (2) To determine the prognostic or diagnostic value for ANP in pregnancies complicated by preeclampsia. (3) To determine if there is an association between ANP, plasma renin activity, and aldosterone in normal pregnancies and those complicated by preeclampsia.

TECHNICAL APPROACH: Patients at risk for preeclampsia are screened for blood pressure weight, plasma renin activity, aldosterone, and atrial natriuretic hormone at 14, 28, 36, 38, 40 weeks and 6 weeks post partum. Samples are obtained after the subjects are at rest - in the lateral recumbent position for 15 minutes.

PROGRESS: No. of Subjects Enrolled - To Date: 42      Reporting Period: 42

Two subjects have withdrawn from the study. One subject was obese and technically difficult to obtain blood samples, and one patient moved off the island. Preliminary data shows that in normal pregnancies atrial natriuretic hormone levels are not changed compared to non-pregnant states. In the few cases in which preeclampsia has developed atrial natriuretic factor is elevated and increases prior to the clinical diagnosis of preeclampsia. Preliminary data was submitted to be presented at the Armed Forces District Meeting of the American College of OB/GYN and accepted. The meeting will be held in November 1989.

### Detail Summary Sheet

Prot No: 8H86	Status: Terminated
TITLE: Infection Prevention in Patients Undergoing Radical Hysterectomy	
Principal Investigator: COL Kunio Miyazawa, MC	
Associate Investigators:	
Department/Section: Obstetrics and Gynecology/Gynecology Oncology Service	
Key Words: hysterectomy; antibiotics; infection	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Terminate

OBJECTIVE: To determine the effectiveness of antibiotics (cefamandole) in preventing infectious morbidity of radical abdominal hysterectomy.

TECHNICAL APPROACH: In a double-blind, randomized study patients receive placebo or iv cefamandole prior to the surgical incision and again two hours later.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No additional cases entered. The current case load is not adequate for statistical analysis. It appears Mandol causes an increased bleeding in operative site. The study should be terminated at this point.

### Detail Summary Sheet

Prot No: 29186	Status: Ongoing
TITLE: GYN-Surgical Training Laboratory Using Animal Models (Swine)	
Principal Investigator: COL Kunio Miyazawa, MC	
Associate Investigators:	
Department/Section: Obstetrics and Gynecology/Gynecology Oncology Service	
Key Words: training	
Funding: FY 88: \$2,281. FY 89: 0	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** To expose TAMC gynecology residents to procedures performed in the management of gynecologic malignancies and to train them in the management of minor urologic and intestinal complications during gynecologic surgery.

**TECHNICAL APPROACH:** Pigs will be preanesthetized with Acepromazine, 0.2 mg/kg IM, and Atropine, 0.04 mg/kg IM; sedated with Ketamine HCl, 22 mg/kg IM; and then either (1) anesthetized with sodium pentobarbital iv to effect with additional pentobarbital given as needed to maintain a surgical plane of anesthesia, or (2) anesthesia induced with sodium pentothal and maintained with nitrous oxide and methoxyflurane. All animals will be intubated. All animals will be euthanatized at the end of the laboratory so no postoperative medication is necessary.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Due to initiation of surgical enhancement training for OB-GYN physicians the study was not conducted last year. It is currently debated if this study should continue or not pending the Army's plan for additional surgical enhancement training.

## Detail Summary Sheet

Prot No: 60H88

Status: Ongoing

**TITLE:** Relief of Repetitive Variable Decelerations by Saline Amnioinfusion in Conjunction with Amniotic Fluid Index Determinations

**Principal Investigator:** CPT Jane Shen-Gunther, MC;

**Associate Investigators:** COL Kunio Miyazawa, MC; MAJ Jerome Kopelman, MC;  
CPT Scott Rose, MC;

**Department/Section:** Obstetrics and Gynecology

**Key Words:** amnioinfusion;

**Funding:** FY 88: NA

FY 89: NA

**Periodic Review Date:** Sep 89

**Gifts:** None

**Decision:** Continue

**OBJECTIVE:** To determine the success rate of amnioinfusion for complete relief of repetitive moderate and severe variable decelerations in conjunction with AFI determinations. To determine the minimum amniotic fluid index achieved by amnioinfusion which will result in complete relief of repetitive variable decelerations. To compare the following outcomes between the infusion-successful and nonsuccessful groups (after segregating the nulliparous and multiparous groups): 1) mode of delivery: vaginal vs. cesarean 2) cesarean section indicated for fetal distress 3) incidence of cord complications: no cord complications vs. identified nuchal cords, occult cord, bandlaid cord, true knot; 4) arterial and venous cord PH results 5) APGAR scores.

**TECHNICAL APPROACH:** After meeting the inclusion criteria, the patient's consent is obtained, and fetal scalp electrode and intrauterine catheter are placed. The preinfusion amniotic fluid index is determined by ultrasound and reassessed every 30 minutes while the infusion is running. A final AFI is determined upon reaching therapeutic success. Amnioinfusion is performed by using normal saline in iv bags and connecting it to the intrauterine catheter by iv tubing and infusing the fluid at the rate of 1000 cc/hr. If fetal distress develops, management is based on scalp pH results. The maximum allowable AFI is set at 20 to prevent the rare complication of polyhydramnios.

**PROGRESS:** No. of Subjects Enrolled - To Date: 14      Reporting Period: 14

No adverse effects have been observed on all subjects to date. Preliminary findings suggest a delta AFI (10.4 cm, range 5.9-14.3), not an absolute postinfusion AFI, must be achieved for amnioinfusion success. Likely causes of failure included cord complications and inadequate retention of infusate in utero. Investigation continues in attempt to confirm our preliminary findings. Paper on preliminary findings of this study is to be presented at the 1989 Armed Forces District Meeting (OB-GYN).

### Detail Summary Sheet

Prot No: 39H89	Status: Ongoing
TITLE: Prevalence of Cytomegalovirus (CMV) Antigenemia in Tripler Army Medical Center Random Blood Donors	
Principal Investigator: CPT Randy L. Hamitt, MC	
Associate Investigators: Dr. Lucille Kimura, Ph.D., 1LT Frank Cross; LTC David Posey, MC	
Department/Section: Pathology and Area Laboratory Services	
Key Words: cytomegalovirus (CMV); antigenemia;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine the prevalence of CMV antigenemia and therefore potential CMV infectivity of random donor blood units. Compare the prevalence of CMV antigenemia to the prevalence of CMV seropositivity in random donors.

**TECHNICAL APPROACH:** The donor center of the TAMC blood bank will collect one green top tube of blood (7-10 ml with sodium heparin) from random consenting donors during blood drives. At least 200 samples will be collected. These samples will be taken to the TAMC hematology lab where they will be processed that same day for CMV antigen testing. Simultaneously, CMV antibody testing will be performed by the blood bank on a separate sample of blood as part of the routine screening of donor units.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

We recently received our materials and have performed the test on control cells. We plan to do our first subjects on 10 Oct 89.



### Detail Summary Sheet

Prot No: 50H89*	Status: Ongoing
TITLE: The Prevalence of Hepatitis A and Hepatitis Non-A, Non-B Antibodies in the Population of American Samoa	
Principal Investigator: COL Robert B. Hill, MC	
Associate Investigators: MAJ Lawton A. Seal, Ph.D., MS; MAJ Mike Langford, DVM; Arwind R. Diwan, Ph.D.	
Department/Section: Pathology and Area Laboratory Services	
Key Words: Hepatitis A; Hepatitis Non-A; Hepatitis Non-B;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine the prevalence of antibodies of the Hepatitis A virus (HAV) and the Non-A, Non-B hepatitis (NANBH) virus(es) in this relatively static population of Pacific Islanders.

TECHNICAL APPROACH: As all the sera for this study has been collected previously by others, no additional serum will be collected, and no other patients will be enrolled in this study. A representative sample of 4,000 - 5,000 sera under evaluation for hantavirus antibodies will be used in these studies. Antibody determinations will be via standard elisa assays presently available or under development by Abbott Diagnostics and we will follow the manufacturer's guidelines for all test procedures. Multiple logistical regression will be employed to evaluate the results.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

\*exempt from committee protocol

New start.

### Detail Summary Sheet

Prot No: 44H87	Status: Ongoing
TITLE: An Investigation of the Possible Transmission of Hepatitis A by Transfusion of Infectious Blood Products at Tripler Army Medical Center	
Principal Investigator: MAJ Lawton A. Seal, Ph.D., MS	
Associate Investigators: CPT Kraig S. Lerud, MC, CPT Michael A. Riel, MC, COL Robert B. Hill, MC	
Department/Section: Department of Pathology & Area Laboratory Services/ Microbiology/Immunology	
Key Words: Hepatitis A virus (HAV)	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To assay for the presence of hepatitis A virus (HAV) in blood products obtained from an infected donor and to monitor the status of the recipient of these potentially infectious products in regard to the presence of HAV specific antibodies (abs) or antigen (agn).

TECHNICAL APPROACH: Viral isolation and immunological assay of patient samples.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

The recipient of the potentially contaminated blood products (platelets) was lost to followup at the 121st Evac Hospital upon her return to the ROK. No additional data are available on this patient. The electron microscopic analysis of the contaminated blood plasma is complete, a draft manuscript has been cleared for submission to a scientific journal. The final draft to be submitted for peer review is nearing completion.

Detail Summary Sheet

Prot No: 30H88	Status: Ongoing
TITLE: SYVA COMPANY - Microtrak HSV Culture Identification Test Premarket Evaluation Trial	
Principal Investigator: MAJ Lawton A. Seal, MS	
Associate Investigators: CPT Kathleen M. Fleet, MC; Ms. Patricia Toyama, M.S. COL Robert B. Hill, MC; COL Joseph C. Woods, MC	
Department/Section: Pathology and Area Laboratory Services	
Key Words: HSV culture;	
Funding: FY 88: NA	FY 89: NA
Gifts: *	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To compare the overall accuracy of the Microtrak HSV Culture Identification Reagent, using a centrifugation-enhanced shell vial, to conventional cell culture methods in use at Tripler for identification of HSV antigen obtained from clinical specimens.

TECHNICAL APPROACH: Laboratory quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

\*Request for outside support referral via USUHS to HMJF. Please note the request via USUHS to HMJF has been withdrawn. TAMC funds have been used to purchase these reagents. Protocols No. 46H88 and No. 30H88 have been merged, and the project is progressing nicely. Presently approximately 130 samples submitted for HSV studies have been analyzed by the Syva HSV Microtrak System and the Pathogene DNA Probe. Another 75-100 samples will be analyzed before the study is completed in the 2nd quarter of FY 90.

### Detail Summary Sheet

Prot No: 46H88	Status: Ongoing
TITLE: Evaluation of the Pathogene Identification Kit - An in situ DNA Probe for Herpes Simplex Virus (HSV)	
Principal Investigator: MAJ Lawton A. Seal, MS	
Associate Investigators: MAJ Merle S. Sprague, MC; COL Joseph C. Woods; COL Robert B. Hill, MC; Ms. Patricia Toyama, M.S.	
Department/Section: Pathology and Area Laboratory Services	
Key Words: Herpes Simplex Virus (HSV)	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare the sensitivity and specificity of this newly developed method of detecting HSV in clinical material to that of a standard culture method as outlined in TAMC Protocol No. 21H88 and a modified culture method as described in TAMC Protocol No. 30H88.

**TECHNICAL APPROACH:** Laboratory quality assurance study.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Protocols No. 46H88 and No. 30H88 have been merged, and the project is progressing nicely. Presently approximately 130 samples submitted for HSV studies have been analyzed by the Syva HSV Microtrak System and the Pathogene DNA Probe. Another 75 - 100 samples will be analyzed before the study is completed in the 2nd quarter of FY 90.

### Detail Summary Sheet

Prot No: 33H89*	Status: Ongoing
TITLE: The Prevalence of <u>Hantavirus</u> Antibody in Humans from Oahu, Samoa and Other Selected Locations in the Pacific	
Principal Investigator: MAJ Lawton A. Seal, MS	
Associate Investigators: MAJ Michael J. Langford, VC	
Department/Section: Pathology & Area Lab Svcs	
Key Words: Hantavirus antibody;	
Funding: FY 88: NA	FY 89: \$2,993.
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine the prevalence of Hantavirus antibody in human population groups located in the Pacific region.

TECHNICAL APPROACH: Serologic testing (EIA) for serum antibodies to the hantavirus (KHF).

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

At this time over 4,000 sera from America Samoa have been tested by EIA for antibodies to the hantavirus. Approximately 5% are positive. Confirmatory tests are pending using a DFA assay. Additional sera will be tested from individuals on Oahu in the near future.

\*Exempt from committee protocol (study done on sera sent from other hospitals).

### Detail Summary Sheet

Prot No: 21H88

Status: Ongoing

TITLE: Use of Maternal Serum IgG Antibody Titer as an Assessment of the Risk of Infection with Herpes Simplex Virus (HSV) to the Unborn Infant

Principal Investigator: MAJ Merle S. Sprague, MC

Associate Investigators: CPT Beau J. Freund, MS; COL Kunio Miyazawa, MC;  
MAJ Jerome N. Kopelman, MC; COL Joseph C. Woods, MC;  
COL Robert B. Hill, MC; CPT Kraig S. Lerud, MC;  
Patricia S. Toyama, M.S.

Department/Section: Pathology and Area Laboratory Services

Key Words: maternal serum igG antibody titer; herpes simplex virus (HSV);

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: \*\$85,639.

Decision: Continue

OBJECTIVE: The primary objective of this project is to test the possibility that obstetricians may be able to simplify their management of patients with herpes simplex virus infection during pregnancy. Instead of cumbersome culturing procedures, results from this project may provide evidence that ordering two sequential herpes serologies during the course of the pregnancy may provide an alternative and easier method of predicting the susceptibility of an infant to herpes neonatorum based on maternal antibody status.

TECHNICAL APPROACH: Laboratory quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

\*Request for outside support referred via USUHS to HMJF.

New start awaiting funds. The new Principal Investigator is COL Robert B. Hill, MC.

### Detail Summary Sheet

Prot No: 2H89*	Status: Completed
TITLE: Postural Demonstration of Two-Dimensional and M-Mode Echocardiographic Mitral Valve Prolapse in Pediatric Patients with Clinical Mitral Valve Prolapse	
Principal Investigator: CPT Mark E. Alexander, MC	
Associate Investigators: LTC Etheridge J. Lovett, MC	
Department/Section: Pediatrics	
Key Words: echocardiographic (ECHO)	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Complete

**OBJECTIVE:** We propose to systematically evaluate two dimensional (2DE) and M-mode (MME) echocardiographic (ECHO) images of the mitral valve leaflets and changes in left-ventricular end diastolic volume (LVEDV) secondary to postural changes in pediatric patients. We will determine if pediatric patients with clinical mitral valve prolapse (MVP) have increased frequency of posturally induced ECHO MVP, compared with pediatric patients referred to ECHO exam without clinical evidence of mitral valve prolapse.

**TECHNICAL APPROACH:** Cooperative pediatric patients 5-18 years old referred for echocardiographic examination were examined in both the supine and the upright positions. Doppler was performed as warranted in the supine position. Left ventricular end-diastolic volume was measured in both positions. Evaluations were read routinely for patient care and then episodically reviewed in a blinded fashion for the presence or absence of mitral valve prolapse in CSE or MME views.

**PROGRESS:** No. of Subjects Enrolled - To Date: 21      Reporting Period: 21

\*Exempt from committee protocol (no extra procedures).

Study currently closed at TAMC - as noted 6/89. Will need to study 10-20 normal children and adolescents under protocol to answer criticisms of manuscript. Abstract presented and paper presented at Tri-Service Pediatric Seminar in Honolulu, 21 March 1989. Manuscript currently in preparation.

### Detail Summary Sheet

Prot No: 3H87	Status: Terminated
TITLE: Serum Phosphate Levels in Necrotizing Enterocolitis of the Newborn	
Principal Investigator: LTC Richard A. Banks, MC	
Associate Investigators: COL Franklin Smith, MC; MAJ Robert Jarrett, MC; MAJ Lynn Whittington, MC	
Department/Section: Pediatrics	
Key Words: neonate, enterocolitis, necrotizing;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

OBJECTIVE: To evaluate the changes in serum phosphate concentrations in neonates with necrotizing enterocolitis (NEC) as a possible marker for the presence and extent of NEC.

TECHNICAL APPROACH: Serum phosphate determination in three groups of patients. NEC, maybe NEC, and not NEC.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There have been no cases of Necrotizing Enterocolitis (NEC) within the last 1-2 years. Request that protocol be discontinued.



## Detail Summary Sheet

Prot No: 4H87	Status: Ongoing
TITLE: Immunosuppressive Therapy with Methylprednisolone, Prednisone, and Azathioprine in Patients with Newly Diagnosed Insulin-Dependent Diabetes Mellitus	
Principal Investigator: LTC Richard A. Banks, MC	
Associate Investigators: Janel Silverstein	
Department/Section: Pediatrics	
Key Words: diabetes mellitus, pediatric, ketoacidosis;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Continue
Gifts: Imuran	

OBJECTIVE: To prevent the progression of autoimmune destruction of the pancreatic islet  $\beta$ -cells in previously undiagnosed diabetic patients presenting with hyperglycemia but without overt ketoacidosis.

TECHNICAL APPROACH: Four randomly assigned treatment arms: 1) steroids and imuran 2) steroids 3) imuran and 4) neither steroids nor imuran; measured against multiple parameters of progression of diabetes.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Study is still in progress at Florida. No candidates have qualified in Hawaii for inclusion. Please continue protocol.

### Detail Summary Sheet

Prot No: 38H87

Status: Ongoing

TITLE: A Comparison of Transdermal Estradiol and Oral Combined Estrogen-Progestin Preparations in the Treatment of Polycystic Ovarian Syndrome

Principal Investigator: LTC Richard A. Banks, MC

Associate Investigators: MAJ Robert M. Lehman, MC;  
MAJ Gerard S. Letterie, MC

Department/Section: Pediatrics

Key Words: polycystic ovarian syndrome;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

OBJECTIVE: To compare the effects of transdermal estradiol and oral sequential estrogen-progestin preparations in patients with polycystic ovarian syndrome, with emphasis placed on relief of symptoms and occurrence of side effects.

TECHNICAL APPROACH: Two-arm treatment trial of approved treatments.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Although intake studies have been initiated on several girls, the inability to guarantee birth control has prevented girls from entry into actual study phase. Please continue protocol.

### Detail Summary Sheet

Prot No: 31H85	Status: Ongoing
TITLE: Treatment of Kawasaki Syndrome with Intravenous Gamma Globulin	
Principal Investigator: COL James W. Bass, MC	
Associate Investigators: Marian E. Melish, M.D.	
Department/Section: Pediatrics	
Key Words: Kawasaki syndrome	
Funding: FY 88: NA	FY 89: NA
Gifts: IV Gamma Globulin	Periodic Review Date: Sep 89
	Decision: Continue

**OBJECTIVE:** Is to evaluate the use and establish the proper dose of intravenous Immuno Globulin for the treatment of children with Kawasaki Syndrome.

**TECHNICAL APPROACH:** Children with Kawasaki Syndrome seen at Tripler Army Medical Center will be offered the opportunity to participate in the study after informed written consent is obtained from the parents. The intravenous immuno globulin will be supplied by Dr. Melish. It will be administered in two different doses as outlined in the protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No subjects have been enrolled to date. We would like to keep this protocol open and should any children with Kawasaki's Syndrome present in the coming year we would like to offer this form of therapy. It already has proven efficacy only the optimal dose is yet to be determined. However, patients would benefit significantly from participation in this study as the intravenous immuno globulin is very costly and the specific preparation used has proved efficacy. In addition, continuation of this study would be in support of the civilian scientific community and the University of Hawaii clinical research endeavors.

### Detail Summary Sheet

Prot No: 14H87	Status: Completed
TITLE: The Evaluation of Early Detection of Group A $\beta$ -hemolytic Streptococci and Treatment in Index Patients and Household Contacts	
Principal Investigator: MAJ James R. Daugh, MC	
Associate Investigators: COL James W. Bass, MC; MAJ Lawton A. Seal, MS;	
Department/Section: Pediatrics	
Key Words: streptococcal infection	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Completed

**OBJECTIVE:** To investigate the potential benefit of early detection and treatment in index patients with group A  $\beta$ -hemolytic streptococcal infection and their household contacts with respect to the attack rate of streptococcal pharyngitis within the household.

**TECHNICAL APPROACH:** Families with a child with group A Strep Pharyngitis C (pharyngitis with a throat culture positive for group A  $\beta$ -hemolytic strep) are randomized into one of two groups. Family members have a throat culture taken at the onset, and then are followed over the ensuing 3 months for any secondary cases of group A strep pharyngitis. Group A families have all household members at the onset receive Penicillin while Group B contacts only receive antimicrodials if they are symptomatic with a positive throat culture. The attack rate of secondary cases of strep pharyngitis is then compared between the two groups.

**PROGRESS:** No. of Subjects Enrolled - To Date: 154    Reporting Period: 154

We had 154 throat cultures submitted total and from that we were not able to show a difference between the prophylactic group and the control. I am currently writing the final draft of the completed project to submit for publication.

Detail Summary Sheet

Prot No: 33H87	Status: Ongoing
TITLE: Ceftriaxone vs. Augmentin for Initial Empirical Therapy of Occult Bacteremia	
Principal Investigator: COL James W. Bass, MC (formerly: MAJ James R. Baugh, MC)	
Associate Investigators:	
Department/Section: Pediatrics	
Key Words: occult bacteremia;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To evaluate the efficacy of a single intramuscular injection of ceftriaxone (75 mg/kg) versus augmentin suspension administered three times a day (40 mg/kg/day divided into three equal doses) in preventing or alleviating the acute infectious morbidity of occult bacteremia in febrile children.

**TECHNICAL APPROACH:** Children 3-36 months of age with documented rectal or tympanic temperature  $\geq 103.0$  and no source of infection by physical exam, chest x-ray, and lab (urinalysis) with informed consent will be randomized to receive empirical therapy of either oral Augmentin or one injection of IM Ceftriaxone. Patients are then followed up in 12-36 hours for evidence of focal infection and blood culture results.

**PROGRESS:** No. of Subjects Enrolled - To Date: 333 Reporting Period: 333

333 patients have been enrolled as of 5 October 1989. There have been 34 (10.2%) positive blood cultures. All have done well and none have developed focal infection. This study is now a multicenter study. It is anticipated that we will need over 1000 patients entered into the study with approximately 100 with positive blood cultures to prove or disprove our hypothesis - this Ceftriaxone will prove superior to Augmentin for patients with occult bacteremia. This will probably take 1-2 more years.

Detail Summary Sheet

Prot No: 40H88	Status: Terminated
TITLE: Infant Pneumonia and Ophthalmia Neonatorum Prevention Project	
Principal Investigator: MAJ James R. Baugh, MC	
Associate Investigators: MAJ Robert R. Wittler, MC; MAJ Lawton Seal, MS; CPT Everett Gayle, MC; Dr. Niven Marchetti; Dr. Margaret Hammerachlag	
Department/Section: Pediatrics	
Key Words: chlamydia;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Terminated

OBJECTIVE: Can the incidence of chlamydia trachomatis infection in the newborn be lowered by a multidosing of regimen of erythromycin ophthalmic ointment.

TECHNICAL APPROACH: Prior to beginning the study, a prevalence survey was done for cervical chlamydia colonization in 100 pregnant women. The survey entailed culture as well as chlamydzyme testing. the results indicate a lower than suspected prevalence which translates into fewer study patients. The study, however, will be done at 2 hospitals which will circumvent Tripler's low study population.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

Project terminated because of Dr. Margaret Hammerachlag, a leading expert in the field of chlamydia research. She stated that data that she and others recently found indicated categorial ineffectiveness of post natal chlamydia prophylaxis.

### Detail Summary Sheet

Prot No: 23H88	Status: Ongoing
TITLE: Predicting Responsiveness to Methylphenidate	
Principal Investigator: Dr. Thomas E. Gallagher, M.D.	
Associate Investigators: Dr. David S. Weiss, Ph.D.	
Department/Section: Pediatrics//Exceptional Family Member Program	
Key Words: methylphenidate(ritalin);	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To identify the variables which predict the responsiveness of Attention Deficit Disorder children to treatment with methylphenidate (Ritalin).

TECHNICAL APPROACH: Multivariant prospective data collection of patient care.

PROGRESS: No. of Subjects Enrolled - To Date: 7      Reporting Period: 7

The study is ongoing and despite slow numbers is advancing with promising results.

### Detail Summary Sheet

Prot No: 16H89	Status: Ongoing
TITLE: Urinary C-peptide Response to Umbilical Arterial Catheter Position in Neonates	
Principal Investigator: CPT Richard T. Hatch, MC	
Associate Investigators: MAJ Robert V. Jarrett, MC; LTC Richard A. Banks, MC	
Department/Section: Pediatrics	
Key Words: umbilical arterial catheter(UAC);	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine if Umbilical Arterial Catheter (UAC) position, (high vs. low) results in different rates of insulin production in neonates.

**TECHNICAL APPROACH:** All infants in which a UAC is to be placed will be eligible for enrollment in the study. The decision as to place a UAC will be made based solely on the infant's clinical condition. Informed consent will be obtained prior to enrollment of all infants. After enrollment, UAC placement will be allocated to either high or low position. The patients will be stratified based on weight. The first child in any weight group will have a high UAC tip placement. Subsequent UACs in each weight group will be alternated sequentially in order to maintain equal numbers of high and low UACs in each weight group. Each child will receive IV fluid (D<sub>10</sub>W) at 80 cc/kg/day (5.55 mg of glucose/kg/min). At 24 hours following placement of the catheter, a 4-6 hour collection of urine will be assayed for C - protein. The urine will be obtained by passive collection with a container placed to catch the urine as the child voids. Capillary dextrosticks will be obtained at a minimum of eight hour intervals during the first 24 hours following placement (as per NICU protocol). The study group will consist of 10 children with low UACs, 10 children with high UACs and 10 children receiving IVF through peripheral veins. Children enrolled in the study will be at no additional risk based on the study. Benefits of being enrolled in the study include prompt recognition of problems involving glucose metabolism, as well as catheter related complications.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5      Reporting Period: 5

We plan to enroll 20 - 30 patients. No data as yet; waiting for sufficient number of samples to arrive.



### Detail Summary Sheet

Prot No: 57H88	Status: Ongoing
TITLE: Combined Utilization of Albuterol, Cromolyn Sodium and Prednisone in the Management of the Dual Phases of Acute Asthma	
Principal Investigator: CPT Wm. Joseph Horam, MC	
Associate Investigators: COL James W. Bass, MC; Dr. Wallace J. Matthews, M.D. CPT Mark E. Alexander, MC	
Department/Section: Pediatrics	
Key Words: acute asthma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine the clinical effectiveness of combining albuterol, cromolyn sodium and prednisone for the outpatient management of the early and late phases of acute asthma.

TECHNICAL APPROACH: Prospective clinical quality assurance study.

PROGRESS: No. of Subjects Enrolled - To Date: 16      Reporting Period: 16

Sixteen patients have been enrolled. No adverse effects have occurred. All patients have responded to outpatient management without subsequent hospitalization. Numbers are too small to conclude.

### Detail Summary Sheet

Prot No: 26H88	Status: Ongoing
TITLE: Vancomycin Dosing Based on Individual Pharmacokinetic Profiles in Neonates	
Principal Investigator: MAJ Robert V. Jarrett, MC	
Associate Investigators: MAJ Thomas J. Kueser, MC; CPT Everett L. Gayle, MC COL James W. Bass, MC	
Department/Section: Pediatrics/Neonatology Service	
Key Words: vancomycin; pharmacokinetic profiles;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine if vancomycin dosing based on individual pharmacokinetic profiles reliably effects desired therapeutic blood levels in neonates.

**TECHNICAL APPROACH:** Clinical quality assurance study of blood levels to pharmacokinetic profiles. Only modification made in approach has been to have pharmacy to supply all vancomycin doses in a unit dose form rather than have nursing draw up doses.

**PROGRESS:** No. of Subjects Enrolled - To Date: 10      Reporting Period: 10

Ten subjects enrolled. One subject withdrawn by principal investigator when initial vancomycin levels found to be toxic. Infant developed transient in BUN and creatinine which quickly reverted to normal. No adverse sequelae on followup. In the ten patients studied thus far, 7/10 peak values were in desired range. 9/10 trough values in desired range. These results are slightly better than previously reported methods.

### Detail Summary Sheet

Prot No: 18H89	Status: Ongoing
TITLE: EXOSURF Pediatric Multiple Dose Prophylaxis Study in High Risk Premature Infants: A Multicenter Trial (P51 Protocol 13)	
Principal Investigator: MAJ Robert V. Jarrett, MC Associate Investigators: MAJ Thomas J. Kueser, MC; MAJ William M. Southgate, MC; MAJ Maureen Jewitt, AN	
Department/Section: Pediatrics/Neonatology Service	
Key Words: EXOSURF; prophylaxis;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To study the efficacy of three artificial surfactant treatment regimens in the prophylactic treatment of premature infants with birth weights between 700 and 1100 grams.

**TECHNICAL APPROACH:** This is a multicenter study plan to enroll 768 patients, with at least 10 patients at TAMC. The effects of two dosage regimens of EXOSURF Pediatric will be studied. Each dosing regimen consists of three intratracheal doses of either EXOSURF Pediatric or air given 12 ( $\pm$ 1) hours apart to infants with birthweights between 700 and 1100 grams. The first dose will be immediately after the infant is stabilized at birth. Patients in Group A will receive three 5cc/kg EXOSURF Pediatric followed by two 5cc/kg doses of air. Patients in Group C will receive three 5cc/kg doses of EXOSURF Pediatric. This protocol may be modified by the results of another multicenter EXOSURF protocol (Protocol 04). In that protocol infants with birthweights between 700 and 1100 grams are randomized to receive a single prophylactic dose 5cc/kg of EXOSURF Pediatric or air at birth. If a single dose of EXOSURF Pediatric proves efficacious, patient entry in Group A of this study will be halted. If it does not prove effective in improving the incidence of intact cardiopulmonary survival, but other important clinical benefits are apparent, patients will continue to be enrolled in Groups A, B, and C. If no benefit is apparent from a single prophylactic dose, Group B will be dropped from this study.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0  
New start.

### Detail Summary Sheet

Prot No: 19H89	Status: Ongoing
TITLE: EXOSURF Pediatric Dose and A-a Gradient Changes in Larger Infants with RDS (P51 Protocol 12)	
Principal Investigator: MAJ Robert V. Jarrett, MC	
Associate Investigators: MAJ Thomas J. Kueser, MC; MAJ William M. Southgate, MC; MAJ Maureen Jewitt, AN	
Department/Section: Pediatrics/Neonatology Service	
Key Words: EXOSURF; respiratory distress syndrome(RDS)	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** The objectives of this study is premature infants with birthweight greater than 1250 grams and established RDS are to evaluate whether a 50% increment or decrement in EXOSURF Pediatric alters the effects of two 5cc/kg doses given 12 hours apart.

**TECHNICAL APPROACH:** This is a multicenter study plan to enroll 240 patients, with at least 10 patients at TAMC. The effects of three dosage regimens of EXOSURF Pediatric will be studied. Each dosing regimen consists of two intratracheal doses of either EXOSURF Pediatric or air given 12 ( $\pm$ 1) hours apart to infants with birthweights greater than 1250 grams and established RDS. The first dose will be given after 2 hours of life but before 24 hours of life. Patients in Group A will receive two 5cc/kg doses of air. Patients in Groups B, C, and D will receive two 2.5cc/kg, 5.0 cc/kg, and 7.5 cc/kg doses of EXOSURF Pediatric, respectively, 12 hours apart.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

New start.

### Detail Summary Sheet

Prot No: 1H89	Status: Ongoing
TITLE: A Comparison of Liquid Nitrogen and Cantharidin in the Treatment of Warts in Children	
Principal Investigator: CPT Peter E. Knott, MC	
Associate Investigators: LTC, Bruce A. Cook, MC	
Department/Section: Pediatrics	
Key Words: cantharidin;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To compare the effects of liquid nitrogen and cantharidin in treating common warts with regard to: efficacy, time to resolution, and side effects.

TECHNICAL APPROACH: Patients age 0-18 years old with more than one common wart are treated with both liquid nitrogen and cantharidin. They are followed at weekly intervals to assess efficacy of treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 32      Reporting Period: 32

To date 32 patients have been entered into this study. The present plan is to enroll a total of 50. Liquid Nitrogen appears to be superior to Cantharidin at this time but additional patients will be needed.

### Detail Summary Sheet

Prot No: 21H86	Status: Completed
TITLE: Prophylactic Intravenous Sandoglobulin for Infections in High-Risk Neonates	
Principal Investigator: MAJ Thomas J. Kueser, MC	
Associate Investigators: MAJ Robert Jarrett, MC	
Department/Section: Pediatric/Neonatology Service	
Key Words: neonatal infection;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: Sandoglobulin	Decision: Completed

**OBJECTIVE:** To determine in a double-blind manner if the prophylactic use of intravenous immune serum globulin compared to an albumin placebo affects the morbidity or mortality of bacterial infections in high-risk neonates.

**TECHNICAL APPROACH:** Fifty consecutive infants meeting criteria for the protocol will be enrolled. The enrolled infants will receive a single IV infusion of either Sandoglobulin, 500 mg/kg, or placebo (albumin, 5 mg/kg). All infants will be monitored during infusion. Infants will be reevaluated on days 9 (postinfusion), 7, 14, and 56 with serum total IgG, opsonic antibody to GBS, physical examination, and documentation of coexisting disease, concomitant medications, antibiotic therapy, blood product transfusions, and the occurrence of septic episodes. Following the eight-week study period, blood collected for immunoelectrophoresis and historical data will be forwarded to WRAIR for evaluation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 45    Reporting Period: 45

45 patients have been enrolled at TAMC. Over 750 patients have been enrolled overall in this multi-collaborative study. No patients have been dropped or withdrawn from the the study. The multi-collaborative study is completed.

### Detail Summary Sheet

Prot No: 9A89	Status: Ongoing
TITLE: Pediatric Intubation Training Utilizing the Feline Model	
Principal Investigator: COL Richard A. Banks, MC (formerly: MAJ Thomas J. Kueser, MC)	
Associate Investigators: COL John D. Roscelli, MC	
Department/Section: Pediatrics	
Key Words: intubation training;	
Funding: FY 88: NA	FY 89: \$3,071.
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** This training is designed to teach physicians and other health care professionals the basic knowledge and endotracheal intubation skills required to resuscitate a neonate (newborn) or infant.

**TECHNICAL APPROACH:** Initially the cats will be anesthetized with ketamine HCL (22 mg/kg intramuscularly) with atropine (0.04 mg/kg, subcutaneously). Additional doses of ketamine may be given if necessary by the Veterinarian staff. The administration and monitoring of the anesthesia will be directly performed by the Veterinarian staff. The students will then visualize the larynx and perform endotracheal intubation using the larynx scope and endotracheal tubes. Anesthesia will be maintained throughout the procedure. Examination gloves will be worn by the students. Animals not suffering significant trauma may be retained for future sessions. If euthanasia is required (determined by the Veterinarian staff), the animals will be euthanized with T-61 given IV, 0.3 ml/kg.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

March 23-25 1989 Tripler AMC held a Pediatric Advanced Life Support (PALS) course which instructed and certified over 55 pediatricians. Four cats were used to teach the technical and mechanical skills of endotracheal intubation. The plan is to offer this course at least yearly and possibly twice a year. Therefore, the above protocol (#9A89) would need to be continued. Currently, no plans for Pediatric Advanced Life Support (PALS), as last course was March 89.

### Detail Summary Sheet

Prot No: 36H87	Status: Completed
TITLE: Identification of the Socially Isolated, Non-delinquent Youth	
Principal Investigator: MAJ Robert M. Lehman, MC	
Associate Investigators: 2LT Helene Jo, RN, ANC(Res)	
Department/Section: Pediatrics/Adolescent Medicine Service	
Key Words: adolescents, self-esteem;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Complete

**OBJECTIVE:** To identify a subgroup of youth that are excluded by their peers and to determine if a difference in perceived self-esteem exists between peer-included and peer-excluded groups.

**TECHNICAL APPROACH:** All patients coming to the adolescent clinic for school physicals are asked if they desire participation. Informed consent obtained. Physicals performed, then patient placed in private room to complete questionnaires. Parents complete their form and place in the box in the waiting room.

**PROGRESS:** No. of Subjects Enrolled - To Date: 140    Reporting Period: 140

Due to the sparsity of patients coming in for regular school physicals without complications that would exclude them from the study, we just achieved about 200 questionnaires completed. However, I am about to ETS to be on faculty at the University of Washington at Seattle in one week. Because of the substantial amount of statistical analysis that needs to be done to complete this project, I will bring the questionnaire with me to analyze at the University of Washington. I expect it should take a few months for me to get settled and then complete the data. At that point I will send you either a summary and termination notice or a prospective article for submission to a Journal. At that point I will be most appreciative of your comments and criticisms and return to me for continued adjustments.



## Detail Summary Sheet

Prot No: 44H89*	Status: Ongoing
TITLE: National Survey of Pediatric Sedation Procedures	
Principal Investigator: CPT Simone Nomizu, MC	
Associate Investigators: COL James W. Bass, MC; CPT Mark Alexander, MC	
Department/Section: Pediatrics	
Key Words: sedation;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To collect data from institutions across the country through questionnaire form regarding the procedures used in the sedation of pediatric patients for diagnostic procedures.

**TECHNICAL APPROACH:** Questionnaires will be sent to various medical centers in order to collect the following data:

- a. selection, route, and dosage of premedication
- b. procedures for which sedation routinely used
- c. age at which sedation routinely used
- d. monitoring procedures
- e. type of health care facility and practice
- f. existence of written guidelines for pediatric sedation
- g. approximate incidence of adverse side effects due to sedation

The data collected will be combined, analyzed and summarized; appropriate conclusions will be made in regards to a national consensus (if one does exist) as to the procedures used in the sedation of pediatric patients for diagnostic procedures. Also, further recommendations will be made for improving currently followed sedation protocols.

**PROGRESS:** No. of Subjects Enrolled - To Date: 82      Reporting Period: 82

\*Exempt from committee protocol.

To date over 82 questionnaires have been received. We are presently totalizing the results. We expect to have this work finalized and ready to submit for presentation and publications with the next 2-3 months. The new Principal Investigator is LTC Bruce A. Cook, MC.

### Detail Summary Sheet

Prot No: 15A88	Status: Completed
TITLE: Inspiratory Flow as a Determinant of Barotrauma in New Zealand White Rabbits Rendered Surfactant Deficient	
Principal Investigator: MAJ Thomas A. Perkins, MC	
Associate Investigators: COL Franklin R. Smith, MC; MAJ Larry J. Godfrey, MC; COL Robert B. Hill, MC.	
Department/Section: Pediatrics/Newborn Medicine Service	
Key Words: surfactant deficient;	
Funding: FY 88: \$6,417. FY 89: \$4,732. Periodic Review Date: Sep 89	
Gifts: None Decision: Completed	

**OBJECTIVE:** To determine if backup IMV during HFOV will prevent atelectasis in adult rabbits rendered surfactant deficient by saline lavage.

**TECHNICAL APPROACH:** Rabbits are initially sedated with IM ketamine and xylazine. Catheters, arterial and venous are placed under local anesthesia with 1% lidocaine. Endotracheal tube is placed by tracheostomy. ABG and hct performed under baseline conditions. FiO2 is increased to 1.0. After 30 min of 100% oxygen and CPAP of 4cm H2O pressure, lavage with warmed saline begins, using 20 to 30 ml aliquots. ABG is checked after every other lavage. PaO2 is reduced to 90 mm Hg. Ventilation studies begin.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

No advantage appears to be offered through the use of backup IMV during HFOV in the saline lavaged adult rabbit.

### Detail Summary Sheet

Prot No: 2A88

Status: Completed

TITLE: The Use of Hyaluronidase in the Treatment of Intravenous Extravasation Injuries

Principal Investigator: CPT William V. Raszka, MC

Associate Investigators: MAJ Thomas K. Kueser, MC, COL Franklin R. Smith, MC  
COL James W. Bass, MC

Department/Section: Pediatrics

Key Words: hyaluronidase; intravenous extravasation injuries;

Funding: FY 88: \$1,440. FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Completed

**OBJECTIVE:** The objective of this blinded pilot study will be to determine if hyaluronidase is effective in reducing the morbidity associated with intravenous extravasation injuries. If hyaluronidase is shown to be effective, we will then determine the maximal time between extravasation of a noxious substance and effective treatment with hyaluronidase.

**TECHNICAL APPROACH:** CaCl<sub>2</sub> in a concentration determined from a pilot phase to reliably produce a full thickness skin necroses, will be injured subcutaneously at 36 sites in 6 juvenile pigs. In a blinded manner either 150 units of hyaluronidase or 1.0cc of normal saline will be circumferentially injured subcutaneously about the injection site. The injection site will be graded by area of induration and area of necrosis to see if hyaluronidase is effective in preventing ulcer formation and skin sloughing.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

This work has been completed. It was presented at the 21st Annual Uniform Services Pediatric Seminar 19-23 March 1989 and the final paper is in preparation for submission for publication.

### Detail Summary Sheet

Prot No: 50H88	Status: Completed
TITLE: Impetigo: Bacteriologic Etiology and Comparison of Effectiveness of Penicillin, Erythromycin and Cephalexin	
Principal Investigator: CPT Michael E. Ruff, MC (formerly: CPT Carl W. Demidovich, MC)	
Associate Investigators: COL James W. Bass, MC	
Department/Section: Pediatrics	
Key Words: impetigo;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Completed

OBJECTIVE: To compare the therapeutic efficacy of penicillin VK versus erythromycin estolate versus cephalexin in the treatment of culture proven superficial skin infections.

TECHNICAL APPROACH: Impetigo, the most common skin infection in children is caused by staph aureus or group A streptococcal bacteria. This study compares treatment efficacy of three randomized antibiotics - erythromycin, penicillin, cephalexin as compared to the specific identified bacteria obtained by culturing the lesion.

PROGRESS: No. of Subjects Enrolled - To Date: 75      Reporting Period: 75

The study was stopped after 75 subjects had been enrolled and it was determined that clinically Penicillin was inferior to Erythromycin and Cephalexin p.05. We are currently in the process of submitting our findings for publication.

### Detail Summary Sheet

Prot No: 26084	Status: Ongoing
TITLE: Use of Sodium Allopurinol to Control Hyperuricemia in Patients With No Therapeutic Alternative	
Principal Investigator: CPT Scott C. Martin, MS	
Associate Investigators: COL Jeffrey L. Berenberg, MC; LTC Bruce A. Cook, MC; LTC William J. Uphouse, MC; MAJ Luke Stapleton, MC	
Department/Section: Pharmacy Service/Oncology	
Key Words: hyperuricemia; allopurinol;	
Funding: FY 88: NA	FY 89: NA
Gifts: Allopurinol	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To provide a water soluble form of allopurinol that can be given intravenously to patients with hyperuricemia who are too ill to take oral medication.

**TECHNICAL APPROACH:** This is a "convenience" protocol to make an uncommonly required dosage form available for use without the need for individual, special exception approval of the committee for each patient. This study also centralizes and simplifies the procedures for requesting the drug for patients. It is anticipated that 1-2 patients a year will be treated on this protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 11      Reporting Period: 2

Two patients enrolled in FY89. Protocol to continue as a "convenience protocol" for use on an as needed basis. Status is ongoing.

### Detail Summary Sheet

Prot No: 15H89 Status: Ongoing

TITLE: A Study of the Relationship Between the Topography of Herniated Lumbar Disks, Lumbar List, and the Side of Pain

Principal Investigator: LTC Richard C. Schreck, SP

Associate Investigators: MAJ Kevin Foley, MC, MAJ Douglas Fellows, MC, Mark Laslett, N.Z.R.P., Maynard Williams, MSC.

Department/Section: Physical Medicine

Key Words: herniated lumbar disks;

Funding: FY 88: NA FY 89: NA Periodic Review Date: Sep 89

Gifts: None Decision: Continue

OBJECTIVE: 1) To test the hypothesis that the relationship between an entrapped lumbar nerve root and a herniated lumbar disk will determine whether a lumbar list will be towards or away from the side of pain. Specifically: that a herniated disk that lies medial to the nerve root will cause a list to the same side as the pain, and a herniated disk that lies lateral to the nerve root will cause a list away from the side of pain. 2) To test the reliability and specificity with which therapists observe a lumbar list.

TECHNICAL APPROACH:

A. INCLUSIONS:

- 1) Consecutive patients diagnosed as having a herniated lumbar disk.
- 2) Those patients who are scheduled to undergo surgery for removal of the herniated lumbar disk.

B. EXCLUSIONS:

- 1) Those who will not sign a standard informed consent form.
- 2) Those patients who are unable (for whatever reason) to complete the study procedures.
- 3) Those whose pain is too severe for them to be subjected to the study procedures.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The number of subjects enrolled in the study as of 29 Sep 89 is 30. There have been 33 subjects asked to participate in the study with three patients electing not to participate. Of the 30 patients in the study, all have completed the procedures with no adverse response.

Early statistical analysis indicates that there is no correlation between the side of pain, lumbar list, and the location of the disk herniation. It is anticipated that another 20 to 30 subjects are needed to make the study statistically significant. There have been no formal presentations of the data or articles written or published.

## Detail Summary Sheet

Prot No: 49H89	Status: Ongoing
TITLE: A Study of the Conservative Approach for the Treatment of the Trigger Finger	
Principal Investigator: MAJ Mary I. Thornton-Vogel, SP	
Associate Investigators: LTC Elizabeth Quinlan, MC; CPT Doug Fugate, MC; LTC Dorothy F. McKennett, SP; SPC Chris Millard; SPC Willie Collins	
Department/Section: Physical Medicine Service	
Key Words: trigger finger;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** 1) To further study the conservative approach for the treatment of trigger finger. Specifically: That no other treatment is necessary for the majority of patients suggesting that this technique should be considered prior to injection or surgery. Hypothesis: This study will clinically support the hypothesis that the described splinting and exercise program reverses the pathological state of the trigger finger in a significant number of cases.

**TECHNICAL APPROACH:** MCP flexion block splint (Burkhalter) to be worn for 3 weeks during waking hours and 3-4 times daily bending PIP and DIP's. If continues to trigger, refer back to Orthopedics for treatment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 3      Reporting Period: 3  
New start.

### Detail Summary Sheet

Prot No: 37H89	Status: Ongoing
TITLE: The Effectiveness of a Community Health Nursing Outreach Program on Reducing the Effect of High-Risk Factors Associated with Child Abuse/Neglect	
Principal Investigator: Teena Edwards, RN, MS	
Associate Investigators: COL Lucille A. Smith, ANC	
Department/Section: Preventive Medicine Service/Community Health Nursing	
Key Words: child abuse/neglect	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

OBJECTIVE: This study will determine the correlation between a community health nursing outreach program and the effects of high-risk factors predisposing to child abuse/neglect within a military community.

TECHNICAL APPROACH: The protocol for this study has remained unchanged. However, because of a greater than 50% staff turnover, lack of staff resources for over a 4-month period, and new staff orientation, the program guidelines have not been strictly adhered to. Therefore, the study period has been delayed by six months.

PROGRESS: No. of Subjects Enrolled - To Date: 61      Reporting Period: 61

Subjects: 61 families are enrolled in study as of 30 September 1989. Due to above technical difficulties, this research study will probably be delayed with a projected completion date of December 1990.



### Detail Summary Sheet

Prot No: 59A88 Status: Ongoing  
TITLE: Resistance of Aedes albopictus in Hawaii to Mosquito Adulticides  
Principal Investigator: LTC Bruce M. Furlow, MS  
Associate Investigators: Mr. Brian Zeichner, U.S. Army Environmental Hygiene  
Agency (USAEHA), Aberdeen Proving Ground, MD.  
Department/Section: Preventive Medicine Service  
Key Words: mosquito; pesticides; Aedes albopictus;  
Funding: FY 88: NA FY 89: \$372. Periodic Review Date: Sep 89  
Gifts: None Decision: Continue

OBJECTIVE: Determine the mortality response of Aedes albopictus mosquito populations to pesticides commonly used in Hawaii.

TECHNICAL APPROACH: Laboratory rat will be anesthetized, hair clipped from a 2" by 5" area of the back, and the animal will be placed in a net sling over a mosquito colony. Hungry, host-seeking female mosquitoes will take a blood meal. The rat will be exposed to mosquitoes until they are satiated and no more mosquitoes are observed feeding up to a maximum of 60 minutes. The rat will be removed and euthanized. The mosquitoes will be provided time for incubation of eggs and appropriate site for deposition of eggs.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Adult mosquitoes are provided blood meals from anesthetized laboratory rats. The next generation of mosquitoes produced by these gravid females are tested against specific insecticides to determine susceptibility.

Results: To date one series of resistance tests have been completed. The mosquito species Aedes albopictus was tested against insecticides malathion and resmethrin. Both insecticides were determined to be effective against this species.

Publications: Memorandum dated 27 February 1989, Subject: Pest Resistance Study No. 16-44-0530-89, Susceptibility Test of the Asian Tiger Mosquito collected from Fort Shafter and Schofield Barracks, Hawaii, 19 November 1988 to 20 January 1989, U.S. Army Environmental Hygiene Agency.

### Detail Summary Sheet

Prot No: 8H88	Status: Ongoing
TITLE: Measles Susceptibility in Hospital Personnel	
Principal Investigator: MAJ Lorrin Pang, MC	
Associate Investigators: COL Joel Brown, MC, MAJ Lawton Seal, MC MAJ Merle Sprague, MC, MAJ Philip Bruno, MC	
Department/Section: Preventive Medicine Service	
Key Words: measles;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: Determine adequacy of ACIP screening (historical) procedure for determination of measles immunity in hospital staff. Also, prevalence of measles immunity in hospital staff will be determined.

TECHNICAL APPROACH: ACIP screening questionnaires are given to newly hired hospital staff. A sensitive and specific ELISA test for measles antibody is simultaneously done on a serum sample to determine accuracy of ACIP criteria.

PROGRESS: No. of Subjects Enrolled - To Date: 94      Reporting Period: 94

Enrollment into the study has been completed (94 subjects). Data is now being analyzed to compare historical account of immunity against serologic evidence. Serology has been completed on all subjects.

## Detail Summary Sheet

Prot No: 51H88

Status: Completed

TITLE: Leptospirosis Presenting as Aseptic Meningitis

Principal Investigator: MAJ Lorrin W. Pang, MC

Associate Investigators: CPT Douglas W. Dothager, MC; COL Joel Brown, MC;  
Patrick Moore, EIS Officer, CDC

Department/Section: Preventive Medicine Service

Key Words: leptospirosis; aseptic meningitis;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Completed

**OBJECTIVE:** The purpose of this study is to examine, retrospectively, the occurrence of leptospirosis among patients given the diagnosis of "aseptic meningitis".

**TECHNICAL APPROACH:** TAMC records were screened retrospectively for the diagnosis of "aseptic meningitis," for the previous 18 months. Patients are asked to enroll and a serum sample is drawn for microagglutination test of leptospirosis antibody by the CDC. If prevalence of antibody is high, controls will be matched and serum tested for comparison.

**PROGRESS:** No. of Subjects Enrolled - To Date: 70      Reporting Period: 70

70 charts were submitted by PAD, TAMC which fulfilled the criteria of aseptic meningitis. Unfortunately those patients seen by the pediatric service did not have lumbar punctures done to confirm this diagnosis. These records, 30, could not be used. Of the remainder only 15 patients could be contacted, the rest having moved off island. All of those contacted permitted blood samples to be taken. One sample was destroyed and not submitted for leptospirosis titers. Of the 14 samples submitted to the CDC one was positive for leptospirosis titer. The findings were presented at the Department of Medicine review of resident projects. It was decided that even though the number of subjects was small the low prevalence of leptospirosis among aseptic meningitis patients in our study population does not warrant further investigation (increased patient numbers, matched controls, or longitudinal study). The State Department of Health conducted a similar study subsequent to the start of this one. Unfortunately, only seven civilians volunteered to have serum tested. Of those tested, three were positive for leptospirosis. It is not known if this difference in leptospirosis rate in patients with the diagnosis of aseptic meningitis represents increased exposure or more missed diagnoses in the civilian sector.

### Detail Summary Sheet

Prot No: 53H88	Status: Completed
TITLE: A Comparison of Brief Group Therapies for Preschool Children: Parent Training vs Group Play Therapy vs Project Group	
Principal Investigator: CPT William S. Evans, Jr., MC; Associate Investigators: CPT Susan A. Black, MC	
Department/Section: Psychiatry	
Key Words: parental training; Group Play therapy; Activity Groups	
Funding: FY 88: NA    FY 89: \$210.	Periodic Review Date: Sep 89
Gifts: None	Decision: Completed

OBJECTIVE: To compare the relative efficacy of parent training, group play therapy vs project group for preschool children (4-6 years of age).

TECHNICAL APPROACH: A comparison of three short-term group therapy approaches to preschool children. Achenbach, Home Situation Questionnaire and Connors will be used as dependent measures. 8 behaviorally or emotionally disordered preschool children were assigned to each treatment modality. Each group ran for 8 weeks, 75 minutes per week. The dependent measurements were administered prior to entry into the study and at completion of the treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 23    Reporting Period: 12

Study was completed 1 February 1989 with 16 participants completing. Overall there was no significant difference in post treatment outcome between groups. There was a trend in the data showing improvement of the Play Therapy Group. The project was presented at the United States Army Medical Department's Annual Child and Family Psychiatry Conference and plans for submission of the article to the Jefferson Journal of Psychiatry are underway.

### Detail Summary Sheet

Prot No: 41H89	Status: Ongoing
TITLE: The Effects of a Multicomponent Smoking Cessation Program	
Principal Investigator: Raymond A. Folen, Ph.D.	
Associate Investigators: MAJ Edward O. Crandell, MS	
Department/Section: Psychiatry/Clinical Psychology Service	
Key Words: smoking cessation;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To assess the effects of a weight control component in a smoking cessation program versus smoking cessation alone on recruitment of participants, attrition rates, cessation rates, and body weight changes.

TECHNICAL APPROACH: All individuals expressing an interest in the on-going smoking cessation program are contacted and, as a possible alternative, offered enrollment in one of the two experimental arms of the project. Subjects expressing an interest in the study are, after giving informed consent, placed in a) the six week behavioral-cognitive smoking cessation arm or b) the six week behavioral-cognitive and weight control component arm of the project. Participants not electing to participate in the study are provided with standard TAMC smoking cessation treatment. No adverse effects are to be reported, and no subjects have been withdrawn or dropped from the study.

PROGRESS: No. of Subjects Enrolled - To Date: 11      Reporting Period: 11

This study continues as proposed.

### Detail Summary Sheet

Prot No: 51H89*	Status: Ongoing
TITLE: The Effect of the Absence of Father on the Patterns of Cosleeping in Military Families in Clinical and Nonclinical Samples	
Principal Investigator: CPT John F. Forbes, MC	
Associate Investigators:	
Department/Section: Psychiatry	
Key Words: cosleeping;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** It is hypothesized that there will be significant differences between the changes in the frequency and pattern of cosleeping in "clinical" vs. "nonclinical" military families. I expect to demonstrate a significantly larger proportion of cosleeping during father's absence in the clinical sample.

**TECHNICAL APPROACH:** To address the question, "does cosleeping cause psychiatric difficulties?" I propose to administer the accompanying questionnaire to parents visiting the Child and Adolescent Psychiatry and Pediatrics Clinic. The questionnaire will explore sleeping habits in military families during times of father's deployment and of father's presence at home. The questionnaires will be anonymous. I will be present in the Pediatrics Clinic to hand out the questionnaires and to answer questions. Those questionnaires administered to parents of the Child and Adolescent Psychiatry Clinic will be mailed out with our other questionnaire in the intake packet, or given to parents by their clinicians. In addition to the questions regarding sleep habits, the questionnaire will have several questions screening for a history of psychiatric treatment or psychiatric problems in the child. Using the responses to these questions, the questionnaires will be sorted into two groups: one with clinical symptoms or presentations, and the other, the control or "healthy" group.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

New start.

\*Exempt from committee protocol.

### Detail Summary Sheet

Prot No: 47H89\*

Status: Ongoing

TITLE: Illicit Drug Use in Active Duty Motor Vehicle Accidents and Severe Trauma

Principal Investigator: CPT Lawrence A. Labbate, MC

Associate Investigators: CPT Douglas Jarvis, MC; CPT William Lynn, MC;  
CPT Andrew Guertler, MC; CPT William Hurley, MC;  
CPT Kraig Lerud, MC

Department/Section: Psychiatry

Key Words: drug;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

OBJECTIVE: To study the prevalence of drug involvement among active duty personnel involved in traumatic accidents.

TECHNICAL APPROACH: Urine sample and blood sample will be used from that normally collected from active duty troops involved in motor vehicle accidents multiple trauma. Urine will be analyzed for the presence of marijuana, cocaine, benzodiazepines, opiates, amphetamines. Blood alcohol level will be measured from the blood sample.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

New start.

\*Exempt from committee protocol.

### Detail Summary Sheet

Prot No: 59H89	Status: Ongoing
TITLE: Nutrition Assessment in Chronically Mentally Ill Patients	
Principal Investigator: MAJ Rickie L. Pullen, MC	
Associate Investigators:	
Department/Section: Psychiatry	
Key Words: nutrition assessment;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

OBJECTIVE: To assess the prevalence of protein malnutrition among chronically mentally ill inpatients.

TECHNICAL APPROACH: All inpatients with chronic mental illness, excluding those with primary drug or alcohol problems will be asked to participate in a nutrition assessment. This will include interview and body measurements performed by the nutrition service and some chemistry studies. Chemistry studies will include: total lymphocyte count, serum albumin, serum transferrin. Data will be collected for six months or N=100.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

New start.



### Detail Summary Sheet

Prot No: 55H89*	Status: Ongoing
TITLE: The Relationship Between Heavy Metal Music and Adolescent Turmoil	
Principal Investigator: CPT Kevin J. Took, MC	
Associate Investigators:	
Department/Section: Psychiatry	
Key Words: heavy metal music; adolescent functioning;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

**OBJECTIVE:** To investigate the association between heavy metal music and adolescent turmoil.

**TECHNICAL APPROACH:** Questionnaires will be given to adolescents, and to their parents. All of the adolescents will be between 12 and 18 years of age, and be patients at TAMC Child and Adolescent Psychiatry Clinic, the TAMC Adolescence Medicine Clinic, or the Adolescent Substance Abuse Counseling Service at Schofield Barracks. By utilizing these three different settings, patients with and without histories of adolescent turmoil will be included. A minimum of 50 subjects will be included in the study (25 HM and 25 NHM listeners). The adolescent questionnaire will focus on demographics, music preferences and listening habits, and current psychosocial functioning. The parental questionnaire will cover the adolescents' past and current psychosocial functioning, as well as questions about family demographics, parental music preferences and parental psychosocial functioning. There will be no identifying data on the questionnaires, only numbers to match the adolescent and parental questionnaires. The adolescents and parents will be separated while filling out the questionnaires and envelopes will be provided to seal the questionnaires after completion. Adolescents will be divided into HM and NHM listeners. To be considered a HM listener, an adolescent will have to list at least two HM bands/performers when asked to name his three favorite bands/performers. For the purposes of this study, a band/performer will be considered HM only if it has appeared in "Metal Edge" magazine and has releases with explicit lyrics about sex, violence (to include suicide and homicide), substance abuse, or Satanism.

**PROGRESS:** No. of Subjects Enrolled - To Date: 20      Reporting Period: 20

\*Exempt from committee protocol.

New start.

Detail Summary Sheet

Prot No: 31H88	Status: Ongoing
TITLE: Stimulant Drug Response in Attention Deficit Disordered Preschoolers	
Principal Investigator: Dr. David S. Weiss, Ph.D.	
Associate Investigators: Dr. Thomas E. Gallagher, M.D.	
Department/Section: Psychiatry	
Key Words: attention deficit disorder; Ritalin;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

OBJECTIVE: To determine the efficacy and side-effects of Ritalin (methylphenidate) and Dexedrine (dextroamphetamine) with preschool children (3-5 years of age) diagnosed as having an Attention Deficit Disorder.

TECHNICAL APPROACH: Children diagnosed with Attention Deficit Disorder, aged 3-5 years, will be given Ritalin, Dexedrine, and placebo in a counter-balanced, double-blind, crossover design (3 weeks in each condition). Ratings will be obtained from parents as well as direct tests of attention and impulsivity on the children, prior to entry in the study and in the last week of each condition. A side effects questionnaire will also be completed by the parents.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The number of subjects enrolled at this point in time is none, as we have had no children in this age range requiring medication.

### Detail Summary Sheet

Prot No: 35H88	Status: Terminated
TITLE: Midfoot Rotational Osteotomy, A Case Repo	
Principal Investigator: CPT Keith S. Albertson, MC	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: osteotomy;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Terminate

OBJECTIVE: Present a case of a patient who had bilateral complete tarsal and metatarsal fusions at age 16 from juvenile rheumatoid arthritis. These spontaneous fusions left both her feet in supination, such that she walked on the lateral aspects of both feet. This resulted in large painful callouses along the entire lateral plantar surface. In an effort to provide the patient with plantargrade feet, osteotomies were performed through the tarsal fusion masses, and then the forefoot rotated about this osteotomy to correct the supination. The method of pre-operative evaluation, surgical approach and technique, and follow-up care will be described.

TECHNICAL APPROACH: Present the case, along with a review of corrective osteotomies of the foot. Collect pertinent information from the patient. Plan routine follow-up with X-Rays as for any other osteotomy patient, including follow-up exams at 6 weeks and six months post procedure. Include actual photographs of patient's feet if consent is given.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

The study has been discontinued per Principal Investigator.

Detail Summary Sheet

Prot No: 36H88	Status: Completed
TITLE: Volar Carpal-Metacarpal Dislocation in an Athlete. A Case Report and Review of the Literature	
Principal Investigator: CPT Keith S. Albertson, MC	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: volar carpal-metacarpal dislocation;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Completed

OBJECTIVE: Present a case with an unusual mechanism for this rare injury, describe a method of treatment which allowed early resumption of athletic activity, and review the literature concerning volar carpal-metacarpal dislocations.

TECHNICAL APPROACH: Describe the mechanism of injury, appearance of the injured limb, method of reduction and closed treatment. Include description of clinical course. X-Ray and physical examinations to be conducted as per routine fracture follow-up, and again at 6 months to determine status after treatment. No additional procedures are required. Photographs may be taken with patient's consent and release. No invasive procedures are planned.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

The study has been completed and has been presented to the Hawaii Orthopaedic Association, Fourth Annual Combined Spring Symposium, June 10, 1989.

### Detail Summary Sheet

Prot No: 32H83	Status: Ongoing
TITLE: Prospective Study of the Use of Urinary D-Lactate Levels in Evaluation of the Acute Abdomen	
Principal Investigator: COL Peter J. Barcia, MC	
Associate Investigators: CPT Susan D. Leshner, MC	
Department/Section: Surgery/General Surgery	
Key Words: urinary D-lactate; acute abdomen;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

OBJECTIVE: To determine the usefulness of urinary D-lactate levels in the evaluation of the acute abdomen.

TECHNICAL APPROACH: Patients evaluated for acute abdominal pain will have urinary D-lactate and creatinine specimens collected every 12 hours from the initial evaluation until four collections postoperatively or it is determined the patient does not have an acute abdomen. In addition, ten preoperatively to serve as controls.

PROGRESS: No. of Subjects Enrolled - To Date: 65 Reporting Period: 1

We have run into major problems in the clinical lab. They are unable to provide any support. We need a tech part time/full time to fully evaluate this modality.

### Detail Summary Sheet

Prot No: 341189	Status: Ongoing
TITLE: Water Sports Injury in Hawaii (Retrospective Study)	
Principal Investigator: CPT Stephen S. Davis, MC	
Associate Investigators: G. Harley Hartung, Ph.D.; Gary A. Okamoto, MD; Raymond M. Taniguchi, MD; Deborah A. Goebert, MS	
Department/Section: Surgery/Orthopedic Service	
Key Words: water sports injury;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** In an effort to determine the extent to which major water sports injuries result in serious disability, a retrospective study of cases from 1985-1988 will be conducted. This information is needed in order to help in the development of and to call attention to planned preventive efforts within the state.

**TECHNICAL APPROACH:** Before attempting to prevent water sports injuries, more information is needed regarding the incidence of such injuries, geographical and activity specific data, and descriptive characteristics of persons likely to sustain serious injury. Medical records will be reviewed for all admitted cases of traumatic brain injury, spinal cord injury, drowning, near drowning, broken bones, internal injuries, and hyperbaric complications for the last 4 years at major hospitals across the state. Injuries which occurred between 1 January 1985 and 31 December 1988 will be reviewed. For those injuries resulting from water sports, data will be abstracted as to demographic characteristics of the patient, diagnosis, cause and location of the injury, resulting disability, length of hospital stay, therapies used in rehabilitation, and discharge status.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

\*Exempt from committee protocol

Study is ongoing. This is a State-wide case registry.

## Detail Summary Sheet

Prot No: 31H87	Status: Completed
TITLE: The Physiologic Response of Antidiuretic Hormone (ADH) and Human Atrial Natriuretic Factor (hANF) to Hypotonic Volume Expansion Secondary to Sorbitol Bladder Irrigation During Transurethral Prostatectomy (TURP)	
Principal Investigator: CPT Paul M. Desmond, MC	
Associate Investigators: MAJ L. Harrison Hassell, MC, LTC Gary Wikert, MC John R. Claybaugh, Ph.D.	
Department/Section: Surgery/Urology Service	
Key Words: antidiuretic hormone; human atrial natriuretic factor;	
Funding: FY 88: \$2,489. FY 89: \$323.	Periodic Review Date: Sep 89
Gifts: None	Decision: Completed

**OBJECTIVE:** To assess the effect of hypotonic volume expansion, secondary to absorbed sorbitol, during TURP on ADH, hANF, renin, aldosterone and fluid and electrolytes. Both uncomplicated TURP procedures and those associated with TUR syndrome (Transurethral Resection Syndrome) will be evaluated. To postulate the roles of ADH, hANF, renin and aldosterone in the pathophysiology of the TUR syndrome in order to: 1) predict which patients are susceptible 2) propose methods during TURP for the avoidance of the syndrome in susceptible patients and 3) provide greater understanding of the pathophysiology of the TUR syndrome so it can be appropriately treated when it occurs.

**TECHNICAL APPROACH:** Venipuncture; multiple blood samples, weights

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

In process of writing a paper. We found that ADH increases during TUR syndrome and is contributory toward its development.

Detail Summary Sheet

Prot No: 20H89 Status: Ongoing

TITLE: Screening for Adenocarcinoma of the Prostate: A Prospective, Randomized Study with Multiple Endpoints

Principal Investigator: COL Martin L. Dresner, MC

Associate Investigators: COL William G. Kennon, MC; LTC Gary A. Wikert, MC

Department/Section: Surgery/Urology

Key Words: adenocarcinoma; prostate;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

OBJECTIVE: To determine if transrectal ultrasound examination of the prostate improves sensitivity of screening evaluations and if early detection of carcinoma of the prostate reduces morbidity and mortality from the disease.

TECHNICAL APPROACH: Volunteers will be randomized to method of exam: rectal alone vs rectal plus transrectal ultrasound. Groups will be compared as to diagnosis of CA of prostate time to metastatic disease, and time to death.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Ongoing, data being collected.



### Detail Summary Sheet

Prot No: 14H89	Status: Ongoing
TITLE: A Randomized Prospective Comparison of Operative Versus Non Operative Treatment of Third Degree Acromioclavicular Separation	
Principal Investigator: CPT Rolf R. Drinhaus, MC	
Associate Investigators: COL Michael J. Fay, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: acromioclavicular separation;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To gain further insight into shoulder function after operative versus nonoperative treatment of third degree Acromioclavicular separations; specifically by comparing the strength of the two shoulders in various motions. This should provide data to help the clinician better determine in which patients open repair should be performed.

**TECHNICAL APPROACH:** Patients with third degree acromioclavicular separations who agree to participate are randomized into operative and nonoperative groups. Operative treatment consists of a Weaver-Dunn acromioplasty with the addition of coracoclavicular suturing when possible. Nonoperative treatment currently consists of a sling or shoulder immobilizer until the discomfort subsides. Patients are evaluated subjectively with a questionnaire, objectively with shoulder strength testing and radiographically. There have been no operative infections, neurovascular complications, problems with screw breakage or other adverse effects to date.

**PROGRESS:** No. of Subjects Enrolled - To Date: 16      Reporting Period: 16

The study is still ongoing. There have been sixteen patients enrolled to date. No subjects have been dropped or withdrawn. There have been three modifications to the protocol: 1) Nonsurgical treatment now consists of a shoulder immobilizer rather than an acromioclavicular harness. 2) Since the surgical exposure allows primary suturing of the ruptured coracoclavicular ligament, this is now done when possible. 3) Finally, since adequate strength and healing of the transposed coracoclavicular ligament occurs by six weeks post-operatively, the coracoclavicular screw will be removed between 6 and 8 weeks, rather than the 10-12 weeks originally planned. One impediment to completion of the study has been the limited resources and personell in the physical therapy department which has made timely shoulder strength testing difficult to arrange. Currently only Major Scoville is able to perform the kin-kom testing.

### Detail Summary Sheet

Prot No: 32H87	Status: Terminated
TITLE: TAMC Protocol No. 32H87: Treatment of Ununited Fractures of Long and Short Bones with Physio-Stim Pulsed Electromagnetic Field Therapy System	
Principal Investigator: COL Michael J. Fay, MC	
Associate Investigators: CPT J. David Pitcher, MC	
Department/Section: Orthopedic Service/Surgery	
Key Words: Physio-stim; ununited fractures;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Terminate

OBJECTIVE: To make available this treatment approach to our patients pending FDA approval. To add to existing information on the safety and efficiency of the PHYSIO-STIM Pulsed Electromagnetic Field Therapy System.

TECHNICAL APPROACH: Patients are selected as eligible for the study in that they have no evidence of fracture healing within four months and have not had surgical intervention in the previous three months.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

We continue to be unable to arrange for a large number of patients to really adequately perform this study. American Medical Electronics, the firm that has been sponsoring this multi-institution study, has canceled it. Their reasons were lack of patients and poor compliance or tolerance of the patient for this method of treatment. All of our patients quit the study early and, indeed, some sought other treatments elsewhere. Principal investigator (COL Michael J. Fay, MC) request removal of this protocol from any further consideration.

### Detail Summary Sheet

Prot No: 25H88	Status: Ongoing
TITLE: The Quadriceps to Hamstring Ratio	
Principal Investigator: COL Michael J. Fay, MC	
Associate Investigators: CPT Charles R. Scoville, SP; SFC Richard W. Weeks; 1LT Leanne M. Pentland, SP; CPT Robbin Rowell, SP.	
Department/Section: Surgery/Orthopedic Service	
Key Words: quadriceps; hamstring ratio;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** The purpose of this study is to determine the normal values for concentric and eccentric quadriceps to hamstring strength ratios in an athletic population, with normal knees, between the ages of 17 and 35.

**TECHNICAL APPROACH:** This study will use infantrymen and assorted support troops from the 25th Infantry Division (Light). We expect that approximately 200 subjects will be tested. We will collect measurements including body type, height, weight, and thigh girths. The subjects will undergo a brief orientation on the purpose of the study and the equipment used. They will then be tested on the Kin-Com. The Kin-Com is a computer driven, hydraulic resisted device, allowing dynamic torsional forces to be recorded at set velocities throughout a pre-selected range of motion using both concentric and eccentric muscular contractions.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8      Reporting Period: 8

1. Lack of cooperation from the 25ID(L) in obtaining soldiers. Division wants us to come there, we cannot move the equipment without major expense and recalibration. Negotiations continue.

2. Lack of personnel trained in operating the Kin-Com device. This limits the number of patients, and when they can be tested.

### Detail Summary Sheet

Prot No: 46A89	Status: Ongoing
TITLE: Use of Fibrin Glue to Achieve Hemostasis in Solid Organ Injury	
Principal Investigator: CPT Scott A. Fengler, MC	
Associate Investigators: LTC Lawrence C. Runke, MC	
Department/Section: Surgery/General Surgery Service	
Key Words: fibrin glue; hemostasis;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

OBJECTIVE: To evaluate the efficacy and safety of the use of Fibrin glue (concentrated human fibrinogen and clotting factors) as a hemostatic agent in solid organ injury.

TECHNICAL APPROACH: An injury will be created of the spleen and fibrin glue will be injected intraparenchymally in an attempt to control bleeding.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

New start.

Detail Summary Sheet

Prot No: 17E78	Status: Terminated
TITLE: Human Implantation of Intraocular Lenses	
Principal Investigator: COL James M. Geiger, Jr., MC	
Associate Investigators:	
Department/Section: Surgery/Ophthalmology	
Key Words: intraocular lenses;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Terminate

**OBJECTIVE:** To study the effects of implantation of intraocular lenses in humans.

**TECHNICAL APPROACH:** Utilization of posterior chamber intraocular lenses requires an extracapsular cataract method with preservation of the posterior lens capsule. Anterior chamber intraocular lenses are used after a routine intracapsular cataract extraction, as secondary implants, and when the posterior capsule is broken during an extracapsular cataract procedure.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

No IRC related surgeries were performed in FY89. Ophthalmology is using only pre-market approved (PMA) intraocular lenses which are not investigational.

### Detail Summary Sheet

Prot No: 40A87	Status: Ongoing
TITLE: Emergent Initiation of Cardiopulmonary Bypass in a Swine Model	
Principal Investigator: CW3 David L. Hahn (formerly: HOLLINGSB, Michael J.)	
Associate Investigators: LTC Greg A. Bowman, MC; MAJ Gary P. Jones, MC; SFC Sam Morgan	
Department/Section: Sugery/Thoracic Surgery Svc	
Key Words: emergent cardiopulmonary bypass;	
Funding: FY 88: \$4,860. FY 89: \$1,441.	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

OBJECTIVE: To introduce and familiarize personnel with the initiation of emergent cardiopulmonary bypass (ECPB) procedure using the swine model.

TECHNICAL APPROACH: Identify problems associated cardiopulmonary bypass e.g., aspiration pneumonia, cardiac damage, and implement appropriate actions, i.e., stablition, cannulation, heparinization and performance of cardiopulmonary bypass.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

To date, 10 pigs have been done and we are requesting that the project be continued.

Detail Summary Sheet

Prot No: 7H89	Status: Terminated
TITLE: Fiberglass Casting Versus Plaster-Of-Paris	
Principal Investigator: MAJ Richard A. Hynes, MC	
Associate Investigators: COL Kent A. Reinker, MC; CPT Steven S. Davis, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: fiberglass; casting;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Terminal

OBJECTIVE: This is a controlled prospective study comparing the clinical efficacy and durability of fiberglass versus plaster cast in 30 active duty members.

TECHNICAL APPROACH: Randomized comparison of cast materials in the Army.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Dropped per request of Principal Investigator.

### Detail Summary Sheet

Prot No: 9H87	Status: Terminated
TITLE: Gait Efficiency of AK Amputees; The Effects of Prosthetic Components	
Principal Investigator: CPT Richard A. Hynes, MC	
Associate Investigators: COL Michael Romash, MC; CPT Beau J. Freund, MSC; Dr. Richard Cirillo, M.D.	
Department/Section: Surgery/Orthopedic Service	
Key Words: AK amputees; prosthetic feet;	
Funding: FY 88: \$50. FY 89: \$1,725.	Periodic Review Date: Sep 89
Gifts: Prosthetists' time	Decision: Terminate

**OBJECTIVE:** (1) To determine if socket design and terminal devices, especially kinetically active terminal devices, change the efficiency of gait of above-knee (AK) amputees, and (2) to establish a scientific basis and experimental program upon which foot terminal devices can be compared using the energy expenditure of gait as a modality for comparison.

**TECHNICAL APPROACH:** Using treadmill to assess energy consumption.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Never performed due to too few patients being identified. Should be dropped as an active protocol.



Detail Summary Sheet

Prot No: 15185	Status: Ongoing
TITLE: Animal Models for Advanced Trauma-Life Support Provider and Instructor Courses	
Principal Investigator: LTC Eric A. Johnson, MC	
Associate Investigators: COL Donald W.S. Yim, MC; MAJ Frank Rogers, MS; MAJ Albert McCullen, VC	
Department/Section: Surgery/General Surgery	
Key Words: advanced trauma life support;	
Funding: FY 88: \$7,174. FY 89: \$1,630. Periodic Review Date: Sep 89	
Gifts: None Decision: Continue	

**OBJECTIVE:** To fulfill the requirement of ATLS Provider and Instructor courses, i.e., to teach physicians a standardized approach to trauma care in the early hours of trauma patient assessment and to teach life-saving skills using animal models.

**TECHNICAL APPROACH:** Goats or pigs are deeply anesthetized with sodium pentobarbital and prepared for surgery. Participants then perform cricothyroidotomy, peritoneal lavage, chest tube placement, pericardiocentesis, and venous cutdown procedures under the close supervision of certified instructors. Animals are euthanatized at the end of the surgery laboratory.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Number of subjects enrolled (from time LTC Johnson became investigator) Aug 88 to date-Goats: 4, physician trainees: 16 (one course ATLS provider on Feb 89). Publications: None - purpose is to train physicians - expect no publishable data.

### Detail Summary Sheet

Prot No: 42A89

Status: Ongoing

TITLE: Experimental Techniques of Liver Surgery

Principal Investigator: CPT Thomas Knuth, MC

Associate Investigators: LTC Lawrence C. Runke, MC

Department/Section: Surgery/General Surgery Service

Key Words: Liver surgery; re-anastomose;

Funding: FY 88: NA

FY 89: \$855.

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** (1) To resect a portion of the liver and re-anastomose that portion in its same location or in another location and/or resect and re-implant the entire liver. (2) To maintain systemic and portal venous blood circulation via temporary catheterization while the liver is removed from the animal's circulation. (3) To re-implant the liver back into the animal resulting in a fully recovered live animal upon completion of the procedure. (4) To assess the liver damage in the post operation period by serial chemical analysis.

**TECHNICAL APPROACH:** We will develop techniques to rapidly mobilize and remove the entire liver from a pig. We will then establish vena caval and portal blood flow to the heart while the liver is out of the body cavity. Techniques will be developed to rapidly resect and/or repair damaged liver tissue and then reimplant the liver into the animal. Techniques will be used and developed to maintain the viability of the liver while out of the body cavity including but not limited to liver hypothermia and perfusion of the liver with nutrient solutions.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA  
As of 14 Sep 89, we have operated on 5 pigs. Our techniques to rapidly mobilize and remove the liver have progressed satisfactorily as have our techniques to re-implant the liver. We have had difficulty maintaining venous flow during our anhepatic period due to clotting in the shunt and in the animal. Because we eventually want to simulate a traumatic injury, we are reluctant to heparinize the animals, therefore, we are re-assessing the feasibility of passive shunts. We may need to try heparinized tubing for shunting or change to a venovenous bypass technique using a pump. So far, we are satisfied with our hypothermic maintenance of the ex-vivo liver but have found that the amount of blood loss encountered with flushing the liver is not well tolerated by the pig. We need transfusion capability or aggressive volume support which we have not practiced so far. Since we feel that our overall technique is still incompatible with survival of the pig we have not yet attempted to recover an animal. Then when this is possible we can simulate the retrohepatic caval injury that this research is about and use techniques to repair the injury. Other residents will be added as co-investigators to continue the project. I plan on visiting Dr. Donald Trunkey's laboratory in December to observe his techniques in a similar liver transplantation project.

### Detail Summary Sheet

Prot No: 60H89	Status: Ongoing
TITLE: Study of Unasyn vs. Cefoxitin for Perioperative Treatment in Abdominal Operations	
Principal Investigator: CPT Thomas E. Knuth, MC	
Associate Investigators:	
Department/Section: Surgery/General Surgery Service	
Key Words: unasyn; cefoxitin;	
Funding: FY'88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** This protocol proposes to study Unasyn as a perioperative and/or therapeutic agent in abdominal surgeries as compared to Cefoxitin.

**TECHNICAL APPROACH:** To use Unasyn or Cefoxitin in a prospective double blinded fashion for the perioperative treatment of a variety of general surgical conditions. Clean contaminated cases will receive preoperative antibiotics only while contaminated and dirty cases will receive a therapeutic course as needed.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

No subjects have yet been enrolled. Final approval by the Human Use Committee is pending. Projected starting time is 1 October 1989.

## Detail Summary Sheet

Prot No: 42H88

**Status:** Ongoing

**TITLE:** Treatment of Lipomatosis with Non-Steroid Anti-inflammatory (NSAI) drugs and Tamoxifen

Principal Investigator: COL Y-Y. Margaret Lee, MC

**Associate Investigators:**

Department/Section: Surgery/General Surgery Service

**Key Words:** tamoxifen; lipomatosis;

Funding: FY 88: NA

**FY 89: NA**

Periodic Review Date: Sep 89

**Gifts: None**

**Decision: Continue**

**OBJECTIVE:** To determine if multiple lipomatosis will respond to Indomethacin, and/or Sulindac and/or Tamoxifen. (There are reports in the literature that reported that colonic polyposis and desmoid tumors did shrink with the treatment of these 3 drugs, either singularly, or in various combinations).

**TECHNICAL APPROACH:** Patient will be given Indomethin first for two months. If there is evidence of shrinkage, the drug will be continued. If there is no response, the drug will be stopped for a month. Then Sulindac will be tried. Tamoxifen will be the third drug to be used. All 3 drugs are included in the TAMC Formulary and conventional doses will be used.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Only one patient has been enrolled in August of 1988. He received Indomethin for two months and decided not to continue. There was no therapeutic effect noted, also no side effect noted. I am looking for another suitable patient to treat.

### Detail Summary Sheet

Prot No: 24H89*	Status: Complete
TITLE: Diagnosis and Treatment of Anorectal Malformations	
Principal Investigator: CPT Susan D.H. Leshner, MC	
Associate Investigators: Dr. Y.C. Huang, MD	
Department/Section: Surgery/General Surgery Service	
Key Words: anorectal malformations;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Completed

**OBJECTIVE:** To examine charts of patients with anorectal malformations seen at TAMC within the last 5 years; to tabulate patient characteristics, methods used in diagnosis, and treatment, and to compare these findings with what is generally known of anorectal malformations.

**TECHNICAL APPROACH:** The charts of 18 patients known to have anorectal malformations seen within the last 5 years will be examined for characteristics delineated in 3. Any available radiological studies will be examined as well.

**PROGRESS:** No. of Subjects Enrolled - To Date: 18      Reporting Period: 18

\*Exempt from CIC/HUC committee protocol.

Completed - meets objective.

### Detail Summary Sheet

Prot No: 25H89*	Status: Ongoing
TITLE: Urinary D-Lactate: A Specific Indicator of Intestinal Ischemia	
Principal Investigator: CPT Susan D.H. Leshner, MC	
Associate Investigators: COL Peter J. Barcia, MC	
Department/Section: Surgery/General Surgery Service	
Key Words: urinary D-lactate;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To demonstrate that elevated urinary D-lactate levels are a useful diagnostic indicator of intestinal ischemia.

**TECHNICAL APPROACH:** Urinary D-lactate values are available from 73 random patients admitted with abdominal pain, and from 8 control patients without abdominal pain. Specimens were obtained prior to any surgical intervention under previous protocols of the above Associate Investigator. (Some serial post-operative specimens were obtained as well, but are not used in this study). Urine was analyzed for D-lactate on a molar basis per unit of creatinine. No statistical analysis of this data has previously been done. Patients will be divided into 2 groups: those found to have ischemic intestinal conditions, and those with other conditions. D-lactate values of the 2 groups will be compared using  $\chi^2$  analysis. If a significant difference is noted, the critical value of urinary D-lactate (outside of which there is the highest likelihood of disease) will be determined.

**PROGRESS:** No. of Subjects Enrolled - To Date: 73      Reporting Period: 73

\*Exempt from committee protocol.

Study is ongoing. New principal investigator will be CPT Martin H. Tieva. Study is hampered by a lack of funds for a laboratory technician to do test in pathology. No tests are being done now.

Detail Summary Sheet

Prot No: 62H88	Status: Ongoing
TITLE: The Role of Ultrasonography in the Diagnosis of Acute Appendicitis: A Prospective Study	
Principal Investigator: CPT Linda Murray, MC (formerly: Rudolph C. C.)	
Associate Investigators: COL Peter Barcia, MC; CPT Gregory Logsdon, MC; MAJ Thomas Leutkehans, MC	
Department/Section: Surgery/General Surgery Service	
Key Words: ultrasonography; acute appendicitis;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To demonstrate that abdominal ultrasound is a useful diagnostic adjunct in cases of acute appendicitis.

TECHNICAL APPROACH: Upon admission to the General Surgery service to rule out appendicitis, real-time ultrasonography of the abdomen is performed in the radiology suite by Dr. Logsdon or Dr. Leutkehans. Results are unavailable to the admitting physician for 12 hours after performance of the exam by which time, clinical decisions have been made and therapy initiated.

PROGRESS: No. of Subjects Enrolled - To Date: 72      Reporting Period: 72

Ongoing study-pending data analysis.

Detail Summary Sheet

Prot No: 56H88	Status: Ongoing
TITLE: The Use of Absorbable (Poly-p-dioxanone) Pins Versus Kirschner Wires for Internal Fixation of Chevron Osteotomies for Hallus Valgus	
Principal Investigator: CPT Craig M. Ono, MC	
Associate Investigators: MAJ Barney Yanklowitz, MS	
Department/Section: Surgery/Orthopedic Service	
Key Words: Kirschner wires; chevron osteotomies;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** Study will describe the utility of the poly-p-dioxanone absorbable pin versus the Kirschner wire in the internal fixation of chevron osteotomies for the correction of the hallux valgus deformity.

**TECHNICAL APPROACH:** The standard (Austin) Chevron bunionectomy/osteotomy will be completed following standard preoperative, intraoperative, and postoperative criteria. The standard Kirschner wire fixation technique requires further minor surgery for its removal. The orthosorb pin fixation technique does not. No less than 27 cases of Orthosorb fixation Chevron procedures will be compared to Kirschner wire fixated cases by objection and subjective parameters: range of motion, foot x-rays, patient satisfaction, complications, clinical presentation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 4

No adverse affects. Two (2) dropped due to P.C.S. orders.

Presently, the Operating Room is out of Orthosorb pins and has ordered enough for 9 more cases. Due to the cost of this item, only 9 Orthosorb pins will be ordered per quarter. It is expected to take 18 to 24 months to complete this study.



## Detail Summary Sheet

Prot No: 50H85	Status: Ongoing
TITLE: Arthroscopic Evaluation of Acute Primary Shoulder Dislocations	
Principal Investigator: CPT J. David Pitcher, Jr., MC	
Associate Investigator: COL Michael J. Fay, MC	
Department/Section: Surgery/Orthopedics	
Key Words: shoulder dislocation; arthroscopy;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To evaluate arthroscopically the lesions associated with shoulder dislocations and correlate these lesions with prognostic indicators relative to recurrent dislocations.

**TECHNICAL APPROACH:** Patient referral requests will be sent to all outlying clinics requesting referral of all patients with initial shoulder dislocations documented by radiographs. Patients entered into the study will be admitted to TAMC Orthopedic Service and placed on the surgery schedule. Arthroscopy will be performed as soon as possible after the injury. Intra-articular pathology will be documented on operative findings data sheets and photographs of pathology will also be maintained in the data file for each patient. Postoperatively, patients will be placed in shoulder immobilizers for three weeks, followed by physical therapy with range of motion and shoulder bridle strengthening program for four weeks. Patients will then be progressed to full duty over a four-week period, and will be followed monthly in Sports Medicine Clinic for six months to one year, documenting clinical progress. Subsequent clinical progress and recurrent dislocation will be correlated with initial pathology documented by arthroscopy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 50      Reporting Period: 50

50 patients have been prospectively identified and randomly placed into two groups. Data collection is currently being accomplished. No additional patients are being enrolled.

### Detail Summary Sheet

Prot No: 31H89	Status: Completed
TITLE: Comparison of Anterior Cruciate Ligament Repair: Arthroscopy and Arthrotomy Perioperative Comparison	
Principal Investigator: MAJ J. David Pitcher, Jr., MC	
Associate Investigators: COL Michael J. Fay, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: anterior cruciate ligament;	
Funding: FY 88: RA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Completed

**OBJECTIVE:** The specific objective of "The Perioperative Comparison" is to focus on short term benefits of the new procedure such as perioperative narcotic requirements as an index of pain, length of hospitalization as an index of early mobilization, estimated blood loss, total tourniquet time, and total operative time as an index of increased perioperative morbidity likelihood.

**TECHNICAL APPROACH:** The last arthroscopically assisted and open ACL reconstructions were reviewed in a chart review.

**PROGRESS:** No. of Subjects Enrolled - To Date: 120    Reporting Period: 120

The patients have been retrospectively reviewed, the data analyzed and the results presented at the 1989 AOA Resident's Conference and the 1989 HOA meeting.

Finalization of the manuscript is pending and the research is complete.

### Detail Summary Sheet

Prot No.	14T85	Status:	Ongoing
TITLE: Microsurgery Training for Orthopaedic Residents Using Rat Vessels			
Principal Investigator: LTC Elizabeth C. Quinlan, MC (Formerly: MAJ Thomas G. Fry, MC)			
Associate Investigators: CPT Steven S. Davis, MC; CPT Rolf R. Drinhaus, MC; CPT Richard M. Cirillo, MC.			
Department/Section: Surgery/Orthopedic Service			
Key Words: training; psychomotor skills;			
Funding: FY 88: NA		FY 89: \$1,088.	Periodic Review Date: Sep 89
Gifts: None			Decision: Continue

**OBJECTIVE:** To train residents in the repair of arteries and veins approximately 1 mm in diameter.

**TECHNICAL APPROACH:** Rats are anesthetized with sodium pentobarbital and one femoral artery and/or vein is transected and then reanastomosed. The wound is observed daily for any complications.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

October 11, 1989 - One orthopaedic resident and two oral surgery staff were trained (resident to repair arteries, veins, nerves; oral surgery staff to repair arteries and nerves). One neurosurgery intern now starting training, and plan is to train at least two more orthopaedic residents this year. One problem has been lack of suture material; lab did not order non-sterile suture, and once we ran out of out-dated sterile sutures, we pilfered suture at \$30 per suture from OR, which needless to say annoyed the OR. SPC Anderson should now have catalog number of non-sterile suture.

### Detail Summary Sheet

Prot No: 19H87

Status Ongoing

TITLE: Peritonsillar Abscess: Treatment with Needle Aspiration and Oral Antibiotics vs. Incision and Drainage and IV Antibiotics

Principal Investigator: MAJ Mark H. Rateink, MC

Associate Investigators: CPT Chip Kava, MC; CPT Richard D. Kopke, MC

Department/Section: Surgery/Otolaryngology Service

Key Words: peritonsillar abscess;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

OBJECTIVE: To establish an effective treatment regimen for peritonsillar abscess which can be utilized by non-otolaryngologists and paraprofessional personnel in a military field setting.

TECHNICAL APPROACH: The peritonsillar area is aspirated three times with a syringe and 18 gauge needle, if pus is found they are enrolled (offered enrollment) in the study.

PROGRESS: No. of Subjects Enrolled - To Date: 18      Reporting Period: 18

The project has been explained to the new residents and staff. New patients will begin to be enrolled. The new Principal Investigator will be CPT Kevin C. Lunde, M.C.

Detail Summary Sheet

Prot No: 7H87	Status: Terminated
TITLE: Post-therapy Hypocalcemia in the Treatment of Patients with Hyperthyroidism	
Principal Investigator: MAJ Mark H. Raterink, MC	
Associate Investigators: MAJ Craig Holland, MC; MAJ Kris Raines, MC; MAJ Harrison Hassell, MC; CPT Donald Moe, MC; CPT Joel Link, MC	
Department/Section: Surgery/Otolaryngology	
Key Words: hypocalcemia, hyperthyroidism;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

OBJECTIVE: To sort out the clinical importance of the first four following mechanisms: (1) post-treatment parathyroid deficiency, (2) thyrotoxic renal magnesium wasting, (3) thyrotoxic osteodystrophy, (4) renal hypercalciuria, and (5) other mechanisms.

TECHNICAL APPROACH: Measurement of blood Free T<sub>4</sub>, T<sub>3</sub>, RIA, TSH thyroid antibodies, Mg, Ca, PTH, Calcitonin and urinary routine chemistry plus Ca, PO<sub>4</sub>, hydroxyproline and cyclic-AMP will be compared with medication dosages.

PROGRESS: No. of Subjects Enrolled - To Date: 4      Reporting Period: 4

Very few patients have been entered into the protocol thus far. Though there have been adequate numbers of Graves patients, most of these have not met criteria for entrance into the study (i.e. patient lives off island; one has other systemic disease). Therefore, the study is terminated.

Detail Summary Sheet

Prot No: 15A87 Status: Ongoing

TITLE: Menisci Energy-Absorbing Characteristics of Pig Hind Knee with Both Static and Dynamic Loads

Principal Investigator: CPT Kenneth Reesor, MC  
Associate Investigators: COL Kent Reinker, MC; MAJ John Uribe, MC;  
Mr. W. Ichimura, Biomedical Engineering Technician

Department/Section: Surgery/Orthopedic Service

Key Words: meniscal injuries;

Funding: FY 88: \$800. FY 89: \$4,212. Periodic Review Date: Sep 89  
Gifts: None Decision: Continue

OBJECTIVE: To establish the energy-absorbing characteristics of the pig knee and to determine if these characteristics are dependent on the percentage of meniscal intact.

TECHNICAL APPROACH: Instrumentation to apply impact loading to isolated pig knees (slaughterhouse donations) will be developed and measurements made of 1) transmitted pressures 2) compression displacements and 3) circumferential elongation or expansion of exercise.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Awaiting equipment fabrication.

### Detail Summary Sheet

Prot No: 40A86	Status: Terminated
TITLE: The Effect of Infusing Embolic Material into the Liver as an Adjunct to Liver Resection in the Pig	
Principal Investigator: CPT Council C. Rudolph, MC	
Associate Investigators: CPT Robert Thomas, MC; MAJ Jean Laberge, MC; COL Y-T Lee, MC; CPT Everett Gayle, MC	
Department/Section: Surgery/General	
Key Words: liver resection, embolic material;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To determine the efficacy of intraoperatively infusing embolic agents into the hepatic circulation prior to liver resection.

**TECHNICAL APPROACH:** Under general anesthesia, the left hepatic branch of the portal vein is isolated and ligated. 2-3 units of Angiostat particles are infused via the isolated vein into the liver. The hepatic artery on the left is ligated. The left lobe of the liver is resected via finger fracture technique. Intraop and postop parameters are measured to gauge blood loss and operative ease.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Study terminated due to departure of investigators.

### Detail Summary Sheet

Prot No: 28H89	Status: Ongoing
TITLE: Clinical Evaluation of a Percutaneous Pneumothorax Catheter Vs. Standard Tube Thoracostomy for the Treatment of Pneumothorax	
Principal Investigator: CPT Bradley J. Roth, MC	
Associate Investigators: LTC Greg A. Bowman, MC	
Department/Section: Surgery/Cardiothoracic Surgery Service	
Key Words: pneumothorax catheter	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** Pneumothorax is a common disease that has routinely been treated with a tube thoracostomy. Recently many studies have shown that this disease may be treated with a much smaller pneumothorax catheter. This study will compare the two types of treatment for non-complicated pneumothorax in an attempt to support the hypothesis that the use of the pneumothorax catheter is less effective than tube thoracostomy.

**TECHNICAL APPROACH:** A chest tube on pneumothorax catheter is placed into the chest for the treatment of pneumothorax. The patient remains in the Protocol for 3 days. If the pneumothorax has not resolved than other treatment modalities are used.

**PROGRESS:** No. of Subjects Enrolled - To Date: 11      Reporting Period: 11  
11 patients enrolled to date. Study progressing well.



### Detail Summary Sheet

Prot No: 49H88	Status: Ongoing
TITLE: The Changing Spacial Relationship of the Patella and Tibia in Normal Knee Motion	
Principal Investigator: CPT James L. Rungee, MC	
Associate Investigators: 2LT Thomas M. DeBerardino, MS; COL Michael J. Fay, MC	
Department/Section: Surgery/Orthopedic Service	
Key Words: normal knee motion;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To radiographically determine and document the motion of the patella in space relative to the tibia during normal knee motion.

**TECHNICAL APPROACH:** Ten (10) volunteers will be picked at random for radiographic evaluation of both knees. To qualify for the study, the participants must have asymptomatic knees, free of instability or other pathologic process as documented by clinical and routine radiographic examination. Lateral radiographs of each knee will be obtained at predetermined degrees of flexion (0, 30, 60, and 90 degrees) as confirmed by goniometric measurement. Using the tibial profile as reference, the spacial motion of the patella will be plotted, measuring specifically:

- a) the antero-posterior excursion of the patella, and
- b) the changing longitudinal tilt of the patella.

Diagrammatic tracings as well as graphical plottings will be utilized to establish the basic characteristic and mean spacial changes of the patello-tibial relationship.

**PROGRESS:** No. of Subjects Enrolled - To Date: 10      Reporting Period: 10

All x-rays have been taken. No ill effects have been reported. Measurements have been performed and the data is currently being analyzed. A large portion of the paper has already been written. Planned completion date is February 1990.

Detail Summary Sheet

Prot No: 52H88	Status: Ongoing
TITLE: Biomechanical Aspects of Olecranonization of the Patella	
Principal Investigator: CPT James L. Rungee, MC	
Associate Investigators: COL Michael J. Fay, MC; Wayne Ichimura, Biomedical Engineer	
Department/Section: Surgery/Orthopedic Service	
Key Words: patella; olecranonization;	
Funding: FY 88: NA	FY 89: \$1,468.
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: a) to study and determine whether olecranonization of the patella actually functions to relieve tension across repairs and reconstructions of the Posterior Cruciate Ligament of the knee, and b) If tension is indeed lessened, to determine the ideal position and method of pin placement that affords limited post-operative knee motion while still protecting the Posterior Cruciate Ligament repair.

TECHNICAL APPROACH: Biomechanical measurements of surgical procedure.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

There have been three trial runs on fresh cadaver specimens. This project was held up, and is now in some danger of never being finished, because of multiple delays getting equipment.

### Detail Summary Sheet

Prot No: 38A89	Status: Ongoing
TITLE: Use of Auto Suture Co. (U.S. Surgical Corp.) Surgical Stapling Instruments in the Training of Residents on Pigs	
Principal Investigator: LTC Lawrence C. Runke, MC	
Associate Investigators:	
Department/Section: Surgery/General Surgery Service	
Key Words: stapling;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To teach proper stapling techniques and precautions to residents using the Auto Suture Co. TA, GIA, EEA instrumentation on the intestines and stomach. End to end, side to side colon and small intestinal anastomoses will be performed using all instruments. Anastomoses between portions of the small intestine and from small intestine to stomach and colon will be done. Anastomoses between the colon and rectum will be done. Transection of the stomach, colon and small intestine will be performed.

**TECHNICAL APPROACH:** Using an abdominal approach, portions of small bowel, large bowel, and stomach will be mobilized enabling the surgeon to perform bowel to bowel and bowel to stomach anastomoses. Closure of the animal will include fascia staples and skin staples.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

This project has not been started due to administrative delays by HSC.

Detail Summary Sheet

Prot No: 6A89	Status: Completed
TITLE: Mode of Ventilation of Effects on Renal Function	
Principal Investigator: CPT David V. Shatz, MC	
Associate Investigators:	
Department/Section: Surgery/General Surgery	
Key Words: renal function;	
Funding: FY 88: NA	FY 89: \$16,276.
Gifts: None	Periodic Review Date: Sep 89
	Decision: Completed

OBJECTIVE: To study the effects on renal function during the currently two most commonly used modes of mechanical ventilation.

TECHNICAL APPROACH: 10 pigs to be studied; placed on ventilator at variable rates of IMV and AC. Renal function on each made will be measured via urine output and chemical analysis, as will cardiac function.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Data collected under the current protocol not consistent subject-to-subject. I will collect remaining outstanding data (hormone assays) and analyze with the hopes to 1) find some publishable consistencies, and 2) re-vamp the protocol to make the data on future trials more consistent (e.g. anesthesia).

### Detail Summary Sheet

Prot No: 45A89 Status: Ongoing

TITLE: Nonanatomic vs Anatomic Liver Resection in Pigs

Principal Investigator: CPT Martin Tieve, MC

Associate Investigators: COL Peter Barcia, MC

Department/Section: Surgery/General Surgery Service

Key Words: non-anatomic liver resection;

Funding: FY 88: NA FY 89: NA Periodic Review Date: Sep 89

Gifts: None Decision: Continue

**OBJECTIVE:** To demonstrate the speed, efficacy and safety of non-anatomic liver resection.

**TECHNICAL APPROACH:** Four pigs will have an anatomic resection and 4 pigs will have a non-anatomic resection. The outcome of the two groups will be compared as well as operative time and blood loss. At the end of the experiment, the animals will be euthanized and a cast made of their vasculature.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

New start; to begin in September 1989.

Detail Summary Sheet

Prot No: 24H88	Status: Ongoing
TITLE: Water Sports Injuries in Hawaii	
Principal Investigator: CPT Gregory G. West, MC	
Associate Investigators: COL Michael J. Fay, MC; G. Harley Hartung, Ph.D.; MAJ Frederick Thaler, MC.	
Department/Section: Surgery/Orthopedics Service	
Key Words: water sports injuries;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To establish a registry of information on water sports injuries in Hawaii.

TECHNICAL APPROACH: Data registry (cooperative state-wide program).

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

The new Principal Investigator is CPT Steven S. Davis, MC. Study is ongoing.

Detail Summary Sheet

Prot No: 28H88	Status: Ongoing
TITLE: Treatment Assessment of Multiple Plantar Warts with Acyclovir	
Principal Investigator: MAJ Barney A. Yanklowitz, MS; Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: plantar warts; acyclovir;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** To discover whether or not an occlusive foot dressing improves the reported results (25%, 38%, 39%) of topical 5% Acyclovir for the treatment of multiple plantar warts after 8 and then 12 weeks.

**TECHNICAL APPROACH:** A clinical investigation including 68 patients ages 2 to 70 (unless pregnant or nursing mother) with a clinical diagnosis of multiple plantar warts (6 or more) or a large surface area (greater than 2.54 cm. diameter) mosaic plantar warts will be treated.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8      Reporting Period: 8

Project began on 6 September 1988 due to review of statistical analysis and patient selection protocol. Patient selection/participation will be low and completion of this project will take 24 months because I only treat one or two patients/month with this severe of wart infection. No patients withdrawn/dropped.

### Detail Summary Sheet

Prot No: 37H88	Status: Ongoing
TITLE: Sonography of Morton's Neuromas	
Principal Investigator: MAJ Barney A. Yanklowitz, VMS	
Associate Investigators:	
Department/Section: Surgery/Orthopedic Service	
Key Words: Morton's neuromas;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To evaluate the size of the third webspace plantar nerve on sonography as a positive predictive indicator of biopsy confirmed Morton's neuromas.

**TECHNICAL APPROACH:** Aggressive conservative therapy for Morton's neuroma includes: examination of duty and recreational footwear; limitation or cessation of hyperextension (of MTPJ) causing activities for six weeks; the use of pedal orthoses (insoles, metatarsal pads) for six weeks; NSAID for 12 weeks; plantar intermetatarsal nerve blocks (local anesthetic and corticosteroid). After failure of aggressive conservative therapy or in the presence of a palpable mass, elective sonography of the affected webspace will be requested by a member of the Orthopedic Service. This routine sonography will be scheduled by appointment and completed by personnel assigned to the Ultrasound Section, Department of Radiology. The resultant hard copy images will be used by the attending Orthopedic staff for operative planning and patient education. Photographs of sonographs and neuromas (in situ or biopsied specimens) will be completed for no more than 48 patients. Neuromas will be confirmed by standard biopsy techniques.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8      Reporting Period: 8

Study approved on 6 September 1988. This study will take at least 18 months. No adverse effects. No patients dropped/withdrawn.



Detail Summary Sheet

Prot No: *22A89 (formerly: 46A85)	Status: Ongoing
TITLE: Altered Consciousness Induced by Overdrainage of Cerebrospinal Fluid	
Principal Investigator: COL Donald W. S. Yim, MC	
Associate Investigators: COL Bernard Robinson, MC, USAR; John R. Claybaugh, Ph.D.; MAJ Jon Graham, MC; MAJ Kevin Foley, MC; MAJ James R. Doty, MC Dr. Robert Jones, MD (Kaiser Medical Center)	
Department/Section: Surgery/Neurosurgery Service	
Key Words: cerebrospinal fluid;	
Funding: FY 88: \$99. FY 89: \$303.	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** To characterize altered consciousness induced by overdrainage of cerebrospinal fluid.

**TECHNICAL APPROACH:** To create an animal model in which coma can be induced by overdrainage of cerebrospinal fluid. Additionally, we hope to be able to demonstrate complete reversal of coma by replacing the volume of CSF removed. Various parameters of vital functions are to be monitored during the investigation. These include evoked responses (auditory, somatosensory, brainstem), blood pressure, electrocardiogram, and pulse rate. Intracranial pressure will also be measured. Cerebral blood flow monitoring is ultimately desired but will not be pursued until a suitable experimental model is confirmed. We hope to characterize any changes in these parameters induced by the test maneuver (CSF Drainage). The test animal will require a craniectomy and insertion of a reservoir to be used for the actual access to the intrathecal compartment chosen for removal of CSF.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

\*NOTE: This protocol supersedes TAMC Protocol No. 46A85

Required equipment has been funded and the equipment is in route.

### Detail Summary Sheet

Prot No: 7H88

Status: Ongoing

TITLE: Urine Detectability in Patients and Physicians of Intranasal 4% Topical Cocaine During Clinical Utilization

Principal Investigator: MAJ Larry A. Zieske, MC

Associate Investigators: MAJ Charles A. Moore, MS; MAJ Richard D. Kopke, MC;  
CPT Charles F. Kava, MC; CPT Eileen M. Mahoney, MC;  
CPT Mark F. Sheridan, MC; CPT Kevin C. Lunde, MC;  
CPT Christopher K. Sinha, MC  
CPT Sharon M. Tomaski, MC.

Department/Section: Surgery/Otolaryngology Service

Key Words: topical cocaine;

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** To determine the detectability of intranasally applied 4% topical cocaine in patients and physicians, applying this in their routine clinical practice. A dose versus time post-exposure graph is to be sought. To determine the protectability of surgical gloves to the applying physician. to determine cutaneous absorption of cocaine by urine drug screening.

**TECHNICAL APPROACH:** To obtain base lines on each physician and patient. To sample patients urine post controlled and documented exposure to cocaine by ENT physicians. The sampling will be: First 6-8 hours post-op and then on a daily basis for 3 days (beyond the normally expected point of negative detection) after any cocaine exposure. Quantification of urine metabolite level will be done as much as possible. Physician samples will also be obtained after use of cocaine with and without latex glove use to check for glove protection and cutaneous absorption. Approximately 24 exposures will be monitored (24 patient and 24 surgeons). The analysis will be by IRA and mass spectrometry. Documenting of all medications will be done (over the counter and prescribed). Chain of custody will be maintained.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Project to start when time available, possibly late 1989 or 1990.

Detail Summary Sheet

Prot No: NSABP B13(84)	Status: Terminated
TITLE: A Protocol to Assess Sequential Methotrexate-5FU in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Negative for Estrogen Receptor	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: breast cancer;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	
Gifts: Fluorouracil and Leucovorin	Decision: Terminate

**OBJECTIVE:** To determine if giving a relatively nontoxic chemotherapy program to women after surgery will decrease the chances of relapse and improve survival.

**TECHNICAL APPROACH:** All eligible patients are randomized to receive (1) chemotherapy with 5-FU and methotrexate twice a month for 1 year or (2) no treatment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 6      Reporting Period: 6

The patients entered have tolerated the chemotherapy very well. National results shows improved disease-free survival (which was significant) in that treated vs. the untreated group. So far there has been no improvement in overall survival. The protocol was recently terminated as it accrued its target number of patients. The results of longer followup are awaited (in terms of survival differences). There was little toxicity with this program.

### Detail Summary Sheet

Prot No: NSABP B14(84)	Status: Terminated
TITLE: A Protocol to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Positive for Estrogen Receptors	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: breast cancer;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Terminate
Gifts: Tamoxifen	

OBJECTIVE: To determine if Tamoxifen given to women after surgery for breast cancer will prolong survival and prevent recurrences.

TECHNICAL APPROACH: All patients who are eligible are randomized to tamoxifen p.o. for 4 years or placebo p.o. for 4 years.

PROGRESS: No. of Subjects Enrolled - To Date: 11      Reporting Period: 11

Nationally the tamoxifen arm of the study have just demonstrated a significantly improved disease-free survival over the placebo arm. So far there has been no difference in overall survival between the 2 arms. The protocol was recently terminated as it accrued its target number of patients. The results of longer followup is awaited (in terms of possible survival differences). There were very few side effects reported (none serious).

### Detail Summary Sheet

Prot No: NSABP B15(84)	Status: Ongoing
TITLE: A Three-Arm Clinical Trial Comparing Short Intensive Chemotherapy With or Without Reinduction Chemotherapy to Conventional CMF in Receptor-Negative Positive-Node Breast Cancer Patients	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: breast cancer;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine if a short course of chemotherapy in the adjuvant setting is as effective as the "standard" six months of CMF. Also, to determine if a later "reinduction" will improve survival.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to one of three treatment groups: (1) Adriamycin and Cytoxan for four cycles, (2) Adriamycin and Cytoxan as above, then, after six months of rest, three cycles of CMF, or (3) six cycles of CMF ("standard" therapy).

PROGRESS: No. of Subjects Enrolled - To Date: 4      Reporting Period: 4

Patients entered to date at TAMC are doing well. No national data available yet.

### Detail Summary Sheet

Prot No: NSABP B16(84)	Status: Terminated
TITLE: A Three-Arm Clinical Trial Comparing Tamoxifen Alone Versus L-PAM, 5-FU, and Tamoxifen Versus Short Intensive Adriamycin-Cyclophosphamide Plus Tamoxifen in Receptor-Positive Node-Positive Breast Cancer Patients	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: breast cancer;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To determine if chemotherapy added to tamoxifen is superior to tamoxifen alone in the adjuvant therapy of receptor-positive breast cancer. Also, to determine which of two chemotherapy regimens, when added to tamoxifen, results in the best survival.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will be randomized to one of three treatments: (1) tamoxifen alone for four years, (2) tamoxifen for four years, plus four cycles of Adriamycin and Cytosan, or (3) tamoxifen for four years, plus L-PAM and 5-FU every six weeks for 17 courses.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 4

Four Tripler patients have been entered to date. It is too early for any analyses. No national data are available.

Detail Summary Sheet

Prot No: NSABP B17(86)	Status: Ongoing
TITLE: A Clinical Trial to Evaluate Natural History and Treatment of Patients with Noninvasive Intraductal Adenocarcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: adenocarcinoma, noninvasive intraductal;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine whether lumpectomy is an effective operation for the treatment of noninvasive breast cancer and if radiation treatments add to that effectiveness.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized after lumpectomy to receive or not receive radiation therapy to the involved breast.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol is still relatively new. We do expect to accrue patients per Dr. Lee in General Surgery Service, Department of Surgery.

### Detail Summary Sheet

Prot No: NSABP B18(89)	Status: Ongoing
TITLE: A Unified Trial to Compare Short Intensive Preoperative Systemic Adriamycin Cyclophosphamide Therapy with Similar Therapy Administered in Conventional Postoperative Fashion	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: adriamycin;cyclophosphamide;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

**OBJECTIVE:** To determine whether 4 courses of preoperative chemotherapy will more effectively prolong disease-free survival and survival than the same 4 courses of chemotherapy given postoperatively in patients with operable breast cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive 4 cycles of adriamycin and cytoxan (day 1 IV every 3 weeks) preoperatively or to receive the same 4 cycles of chemotherapy postoperatively. Tamoxifen will be given twice a day after surgery to all patients age 50 years or more (regardless of which chemotherapy group they are assigned).

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol just opened. No data are available yet.



Detail Summary Sheet

Prot No: NSABP B19(89)	Status: Ongoing
TITLE: A Clinical Trial to Compare Sequential Methotrexate 5-Fluorouracil (M-F) with Conventional CMF in Primary Breast Cancer Patients with Negative Nodes and Estrogen Receptor Negative Tumors	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: methotrexate; 5-fluorouracil;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine if 6 cycles of Cyclophosphamide, Methotrexate and 5-fluorouracil is as effective or more effective than 6 cycles of sequential Methotrexate, 5-fluorouracil followed by Leucovorin in the prolongation of disease-free survival and survival in resected, node negative breast cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized post-op to receive either 1) 6 cycles of Cyclophosphamide, Methotrexate and 5-fluorouracil or 2) 6 cycles of sequential Methotrexate 5-fluorouracil (with Leucovorin).

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

This study opened very recently and no data are available yet.

Detail Summary Sheet

Prot No: NSABP B20(89)	Status: Ongoing
TITLE: A Clinical Trial to Determine the Worth of Chemotherapy and Tamoxifen over Tamoxifen Alone in the Management of Patients with Primary Invasive Breast Cancer, Negative Axillary Nodes and Estrogen Receptor Positive Tumors	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: tamoxifen;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine if Methotrexate plus 5-fluorouracil plus Leucovorin plus Tamoxifen is more effective in terms of disease-free survival and survival than Tamoxifen alone in node negative estrogen receptor positive resected breast cancer. Also to determine if Cyclophosphamide plus Methotrexate plus 5-fluorouracil (CMF) plus Tamoxifen is more effective than Tamoxifen alone. Finally, to compare the 2 chemo programs to each other.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) Tamoxifen alone for 5 years, 2) Methotrexate, 5-fluorouracil and Leucovorin every 4 weeks for 6 cycles + Tamoxifen as above, or 3) CMF every 4 weeks for 6 cycles + Tamoxifen as above.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol just opened and no data are available yet.

Detail Summary Sheet

Prot No: NSABP B-22(89)

Status: Ongoing

TITLE: A Clinical Trial to Evaluate the Effect of Dose Intensification and Increased Cumulative Dose of Postoperative Adriamycin-Cyclophosphamide (AC) Therapy on the Disease-Free Survival and Survival of Patients with Primary Breast Cancer and Positive Axillary Nodes

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS;  
LTC Yeu-Tsu Margaret Lee, MC;  
MAJ Marianne M. Young, MC

Department/Section: Medicine/Medical Hematology-Oncology Service

Key Words: adriamycin-cyclophosphamide (AC);

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

OBJECTIVE: To determine whether giving larger doses of CTX is the first 2 or 4 cycles of adjuvant CTX and ADRIA chemotherapy will improve the survival of breast cancer patients over patients given standard doses of those 2 drugs for 4 cycles. To determine if larger doses of CTX in all 4 cycles is superior to 4 cycles at standard doses.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1 of 3 dose schedules of CTX and ADRIA IV day one every 3 weeks for 4 cycles (i.e., 12 weeks). Patients age 50 and over will also receive Tamoxifen 10 mg p.o. twice daily for 5 years.

PROGRESS: No. of Subjects Enrolled - To Date: 0

Reporting Period: 0

This protocol just opened and no data are available yet.

### Detail Summary Sheet

Prot No: POG 8104(83)	Status: Ongoing
TITLE: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: neuroblastoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: VM-26	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** Attempts to reduce later complications by separating by age and stage those patients that require surgery only, surgery and chemotherapy, surgery, chemotherapy, and radiation therapy, etc.

**TECHNICAL APPROACH:** Pediatric patients and adolescent patients under the age of 18 with neuroblastoma are eligible for enrollment in this study. Treatment will be as outlined in the study protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5      Reporting Period: 5

With the opening of new POG protocols, this study has now been limited to:

- 1) Newly diagnosed Stage A.
- 2) Newly diagnosed Stage C. (Age >365 days).
- 3) Newly diagnosed Stage Ds (Surgery only option).
- \*4) Stage A Recurrence (if >365 days).
- \*5) Stage A Recurrence (if <365 days, Stage C or D at recurrence).
- \*6) Stage B, C, D failure.

\*All recurrences must have been previously registered on POG 8104.

No new patients have been registered on this study during the last year. At this time the only arms remaining open to patient registration are Stage A and DS surgery only. The remaining arms have been terminated because of sufficient patient accrual to answer the study question. A manuscript on Stage A patients was published in the Aug 88 Journal of Clinical Oncology. Manuscripts for Stage B and D are in progress. Included is data from Stage C patients only.

### Detail Summary Sheet

Prot No: POG 8158(83)	Status: Ongoing
TITLE: NWTs Long Term Follow-up Study	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: Wilm's tumor;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

**OBJECTIVE:** To examine the late consequences of successful treatment given for Wilms' tumor.

**TECHNICAL APPROACH:** Pediatric patients and adolescent patients under 18 years of age with Wilms' tumor will be eligible. Treatment will be as outlined in the study protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been entered into this protocol as yet. This is a non therapeutic study designed to gather epidemiologic and late effects data on long term (>5yrs) survivors of Wilm's tumor. No Tripler patients have been registered to date. Nationally 154 patient registrants have been accrued. No detailed results are available yet and the study remains open.

An abstract has been published AACR 27:204 1986.

### Detail Summary Sheet

Prot No: PUG 8346(85)	Status: Terminated
TITLE: Comprehensive Therapy for Ewing's Sarcoma: Tailored Versus Standard Radiation Therapy, Phase III	
Principal Investigator: LTC Bruce A. Cook, MC;	
Associate Investigators: LTC Joseph Woods, MC; COL Peter Barcia, MC	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: Ewing's sarcoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Terminated

**OBJECTIVE:** This study is directed toward comprehensive care of the child with Ewing's Sarcoma. Several questions are being asked in this study, but there are essentially two major points to the investigation: (1) Do sequential cyclophosphamide and Adriamycin produce complete or partial responses as well as group and historical controls? (2) Is local tumor control achieved as well with radiation therapy to a small field (tumor plus margin) as compared to the standard whole bone field?

**TECHNICAL APPROACH:** After initial induction chemotherapy, patients are evaluated to assess completeness of response. Patients are then randomized to small field or whole bone radiation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One TAMC patient have been registered on this protocol, it remains open to patient entry. One abstract has been accepted utilizing data from this study - SIOP - 1985. At 48 months follow-up survival in all patients is 60%.

This study was terminated 7 November 1988 because patient accrual was adequate to answer the study questions. One hundred eighty four patients have been entered on study and 162 are fully eligible. Grade IV toxicity is noted. Outcome by primary site and size of primary is included (table 6&7). Figure 1 represents event free survival and survival for eligible patients managed primarily by chemotherapy and XRT. Figure 3 includes all eligible patients analyzed for survival

### Detail Summary Sheet

Prot No: POG 8451(86)	Status: Ongoing
TITLE: Intergroup Rhabdomyosarcoma - Study III	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatric/Hematology-Oncology Service	
Key Words: rhabdomyosarcoma;	
Funding: FY 88: NA FY 89: NA	Periodic Review Date: Sep 89
Gifts: Drugs	Decision: Continue

**OBJECTIVE:** This protocol is the new Intergroup Rhabdomyosarcoma III study designed to provide definitive care to all new cases of rhabdomyosarcoma less than 21 years of age.

**TECHNICAL APPROACH:** Multiagent chemotherapy and radiotherapy tailored to: site of disease, histologic subtype and stage of disease. Results will be compared to IRS I & II (historical controls).

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One Tripler patient has been enrolled in this study. The patient is 20 months into therapy and has done very well with minimal toxicity. Nationally 256 patients have been entered in the study. No abstracts or publications have been published at this time.

Nine hundred twenty two patients have been registered nationally with 835 being eligible for evaluation. The results for randomized treatments are still blinded. There is an ASCO 1989 abstract.

### Detail Summary Sheet

Prot No: POG 8493(85)	Status: Terminated
TITLE: Infant Leukemia Protocol, Group-Wide Pilot	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators: LTC Joseph C. Woods, MC	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: Infant Leukemia;	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: VM-26	Decision: Terminate

**OBJECTIVE:** To study biologic differences of acute lymphocytic leukemia (ALL) in infants and improve the very poor disease-free survival in this group. A major objective is to identify toxicities and determine criteria for dose modification in infants.

**TECHNICAL APPROACH:** All patients will be treated with the same regimen and response rates will be compared to 75 controls from POG's previous ALL studies.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1    Reporting Period: 1

No TAMC patients have been enrolled in this study, which remains open at this time.

Abstracts: Blood 6S(S): 252A, 1986.  
Proc. ASCO Vol. 6:161, 1987.

Study terminated 18 February 1989 because enough patients had been entered to answer the study question. Statistical analysis is ongoing, however, the following points can be made: (1) Induction of remission was 96% which was significantly better than historical controls ( $p=.005$ ). (2) Disease free survival (DFS) is superior to historical controls; two year DFS is 27%. (3), Among the prognostic factors studied significant adverse factors include age <9 mo, pre-B phenotype and WBC count >50,000. (4) Toxicity. Considerable hematologic toxicity was observed with frequent serious infections. The recognition of infants with low serum IgG levels prompted the addition of the use of IV immune globulin. This appears to have reduced the incidence of infection.



### Detail Summary Sheet

Prot No: POG 8552(85)	Status: Ongoing
TITLE: A Case Control Study of Childhood Rhabdomyosarcoma	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: rhabdomyosarcoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To evaluate the relationships between environmental exposures, gestational factors, and genetic factors in childhood rhabdomyosarcoma.

**TECHNICAL APPROACH:** Data will be collected by telephone interview conducted by the Intergroup Rhabdomyosarcoma Group and by a questionnaire. These data will be correlated with biologic data collected from treatment protocol forms.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been enrolled on this study to date. It remains open.

56 patients registered nationally.

Publication: J Clin Oncology 2:670-675, 1984.  
Med Hypotheses 12:17-20, 1983.  
J Natl Cancer Inst 68(1):107-113, 1982

Seventy nine patients have been enrolled nationally. No specific data except preliminary reports and methods as noted in publications above.

### Detail Summary Sheet

Prot No: POG 8561(R7)	Status: Terminated
TITLE: Phase II Study of 6-Mercaptopurine Administered as an Intravenous Infusion for Malignant Solid tumors and Acute Leukemia	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology/Oncology Service	
Key Words: acute leukemia; 6-Mercaptopurine;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Terminate

**OBJECTIVE:** a. To determine response rate of children with advanced malignant disease for whom no effective anti-cancer therapy is known to treatment with 6-mercaptopurine (6-MP) administered as a 48-hour IV infusion.  
b. to further assess the toxicity in a larger group of children.

**TECHNICAL APPROACH:** a. Patients will be given 6-MP,  $1.2 \text{ gm/M}^2/\text{day} \times 48$  hours by continuous infusion. Dilution =  $1 \text{ mg/ml}$  as a 48-hr infusion at the dose rate of  $50 \text{ mg/M}^2/\text{hr}$ . b. Treatment frequency: Cycles will be repeated every 21 days if counts are adequate: ANC must be  $\geq 1500 \text{ } \mu\text{l}$  and platelets  $> 100,000/\text{ } \mu\text{l}$  unless BM compromised.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Nationally 108 patients have been entered in this study. Toxicity has been as expected, pancytopenia, alopecia, stomatitis and nausea/vomiting. Some hepatic and renal toxicity of grade 2-3 have been reported but the majority have not experienced toxicity in this area.

This study has been terminated because patient accrual has been adequate to answer the study question. Statistical analysis of results are in progress.

### Detail Summary Sheet

Prot No: POG 8600/01/02 (86)	Status: Ongoing
TITLE: Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood (ALinC 14C)	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: Leukemia;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To thoroughly classify by laboratory methods the type of leukemia in children newly diagnosed with ALL, to see if better characterization of newly diagnosed leukemia can better define different prognostic groups. To provide comprehensive care of children newly diagnosed with ALL.

**TECHNICAL APPROACH:** Multiagent chemotherapy of ALL. Results of therapy will be compared to previous POG protocols for therapy of ALL which serve as historical controls. Data will be used to construct new treatment regimens based on prognostic groups and previous therapeutic studies.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5      Reporting Period: 2

Three Pediatric patients enrolled at this time. 886 patients have been entered into this study nationally. It appears that chromosome Ploidy, is an important prognostic factor. Event free survival for all patients at 18 months follow-up is about 80%.

Publication: Blood 70(6): 1962-1965, 1987  
Blood 72(1): 229-307, 1988

POG 8600 has enrolled 1,511 patients nationally the following factors have been found to be prognostic: (1) Within non-T, non-B: White count, age, ploidy, MY10. (2) Within T: No significant factors. (3) Pre-B is not a significant factor at this time. 8602 Summary: (1) Overall remission induction rate is 97%. (2) Pre-B has not been a significant adverse prognostic factor, no significant difference in event free survival between Arm D and the other arms. (3) CNS relapses are rare; no isolated testicular relapses have yet occurred and marrow relapses are low. (4) Two year event free survival is 84%. (5) Duke MY10 and St. Jude Ploidy are significant prognostic factors for early event free survival. (6) Toxicity concerns have been infections, allergic reactions, transaminase elevations and hematologic suppression.

### Detail Summary Sheet

Prot No: PUG 8617/18(87)	Status: Ongoing
TITLE: Therapy for B-Cell Acute Lymphoblastic Leukemia and Advanced Diffuse Undifferentiated Lymphomas	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology Oncology Service	
Key Words: acute lymphocytic leukemia;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** a. To estimate the complete remission (CR) rate in patients with Stage IV diffuse undifferentiated non-Hodgkin's lymphoma (DU NHL) and B-cell acute lymphocytic leukemia (B-ALL) with a new schedule of administration of three active agents: "split-dose" cyclophosphamide (cyclo) + Adriamycin (Adria) + vincristine (VCR). b. To estimate chemotherapeutic cure rate in State IV DU NHL and B-ALL with a brief (6 months) intensive rotational chemotherapy program designed to confer greater protection against central nervous system (CNS) disease and marrow relapse. c. To estimate the reinduction rate and disease-free survival rate for patients in relapse with non-lymphoblastic lymphoma.

**TECHNICAL APPROACH:** All patients are treated with four cycles of high dose cytoxan, vincristine, daunomycin plus IT therapy with MTX and ARA-C alternated with 4 cycles of high dose MTX, high dose ARA-C and IT MTX and ARA-C.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

Fourty-two patients have been entered on this study nationally with 38 being considered fully evaluable. Of 23 evaluable B-cell ALL 13 remain in continuous complete remission. Of the 15 evaluable stage IV lymphoma 11 remain in continuous complete remission. Toxicity has been encountered including 4 deaths from fungal infectious and one death off therapy from pneumocystis carinii. Reversible myelopathy has also been encountered.

### Detail Summary Sheet

Prot No: POG 8631(87)	Status: Ongoing
TITLE: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs. Standard Dose Irradiation	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology/Oncology Service	
Key Words: medulloblastoma; radiation;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

**OBJECTIVE:** To see if reduced irradiation to the spinal contents and supratentorial area of the brain can achieve an equal rate of disease-free survival and a lesser degree of psychomotor retardation as compared to standard dose irradiation.

**TECHNICAL APPROACH:** All registered children will be randomized into one of two treatment arms (a) Arm 1--3600 rads to whole brain and spinal contents plus an additional 1800 rads to posterior fossa, and (b) Arm 2--2340 rads to whole brain and spinal contents plus an additional 3060 rads to posterior fossa.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No Tripler patients have been enrolled in this study. Nationally a total of 44 patients have been registered. Toxicity has been mild. Too early in the study to determine statistical differences.

### Detail Summary Sheet

Prot No: POG 8633/34(89) Status: Ongoing

TITLE: The Treatment of Children Less Than Three Years of Age with Malignant Brain Tumors Using Postoperative Chemotherapy and Delayed Irradiation

Principal Investigator: LTC Bruce A. Cook, MC  
Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: postoperative chemotherapy;

Funding: FY 88: NA FY 89: NA Periodic Review Date: Sep 89  
Gifts: None Decision: Continue

**OBJECTIVE:** To determine if the use of postoperative chemotherapy in children less than 36 months of age with malignant brain tumors will allow for the delay of cranial irradiation for 12 months in children 2-3 years at diagnosis and 24 months for those less than two years old. To estimate the response (CR or PR) to two cycles of cyclophosphamide and vincristine in children with measurable tumor at the initiation of chemotherapy. To estimate the objective response rate (CR, PR, SD) and disease control interval with this multi-agent chemotherapy regimens. To estimate the disease control interval, recurrent-free survival, and survival for children following chemotherapy and radiation therapy in each disease category. To establish the acute and chronic toxicities of this approach, including neurological, neuropsychological, endocrine, and somatic effects.

**TECHNICAL APPROACH:** Children will be randomized to one of two treatment programs based on age at diagnosis. Chemotherapy will consist of vincristine (.065 mg/kg) and cytoxan (65 mg/kg) alternated with cisplatin (4 mg/kg) and VP-16 (6.5 mg/kg) as per the attached treatment schema. Upon completion of chemotherapy, children with a complete response will receive radiotherapy. Children with stable disease or a partial response may have a second surgical procedure followed by radiotherapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1 Reporting Period: 1

One TAMC patient enrolled during this evaluation period demonstrated persistent disease following treatment on 8633. He has just completed radiation therapy per POG 8634.

POG April 89 report indicates 120 patients enrolled as of Nov 1988: 78 in 0-23 month age group, 37 in 24-36 month age group. Thirty five patients went off study for progressive disease but only 17 were registered on 8634. Overall survival at 2 years are essentially the same for each age group. See attached survival figures to include evaluation by histologic types. It is too early for analysis of response on 8634.

### Detail Summary Sheet

Prot No: POG 8650(89)	Status: Ongoing
TITLE: National Wilms' Tumor Study 4	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Pediatric Hematology/Oncology Section	
Key Words: Wilms' tumor;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare the relapse-free and overall survival rates of 1) stages I and II FH patients and stage I anaplastic patients treated with conventional CT vs pulse-intensive CT with vincristine and actinomycin D; 2) patients with stage III and IV FH Wilms' and stage I-IV CCSK who are treated with conventional CT vs pulse-intensive CT with vincristine, actinomycin D, and Adriamycin + XRT; 3) patients with stage II-IV anaplastic Wilms' who are treated with vincristine, actinomycin D, and Adriamycin vs those three drugs in combination with cyclophosphamide and XRT; 4) patients with stage II-IV FH and stage I-IV CCSK who are treated for 6 mos vs approximately 15 mos post-nephrectomy.

**TECHNICAL APPROACH:** Patients with stage I-IV favorable histology (FH) or stage I-IV anaplastic Wilms' tumor, or stage I-IV clear cell sarcoma of the kidney (CCSK). Must have undergone nephrectomy, but no prior CT or XRT. Must be <16 yrs of age. **Followed:** Must have stage I-IV anaplastic Wilms' tumor, stage I-IV CCSK, or stage I-IV malignant rhabdoid tumor of the kidney. Must have a medical or social reason precluding randomization (see Sec. 4.122), including age >16 yrs. **Registered:** 1) Patients with histologically confirmed mesoblastic nephroma or diagnosis other than Wilms', anaplastic, clear cell, or rhabdoid tumor (to include those patients who have been previously treated or who have died post-op); OR 2) patients who have received prior therapy

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

Nationally 310 patients have been registered. No statistical analysis available at this time.

### Detail Summary Sheet

Prot No: POG 8651(86)	Status: Ongoing
TITLE: Osteosarcoma Study #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Nonmetastatic Osteosarcoma, Phase III	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatric/Hematology-Oncology Service	
Key Words: osteosarcoma, chemotherapy;	
Funding: FY 88: NA	FY 89: NA
Gifts: Methotrexate	Periodic Review Date: Sep 89
	Decision: Continue

**OBJECTIVE:** To compare delayed surgery group to their immediate surgery controls to see if (1) those patients considered ineligible for limb salvage can be converted to candidates for limb salvage, and (2) preoperative chemotherapy improves disease-free survival.

**TECHNICAL APPROACH:** Multiagent chemotherapy utilizing methotrexate, adriamycin, cis-platinum, Bleomycin, Actinomycin-D and Cytosan over 42 weeks. One half of patients are randomized to immediate therapy. The remainder receive 10 weeks of adjuvant chemotherapy prior to definitive surgery.

**PROGRESS:** No. of Subjects Enrolled - To Date: 3      Reporting Period: 0

3 TAMC patients have been enrolled in this study. Toxicity has been primarily hematopoietic. Bleomycin induced (transient) pulmonary toxicity was noted in one patient. Two patients are alive and well with no evidence of active disease. One TAMC patient has died of recurrent disease.

As of POG April 89 report, 43 patients have been registered: 21 to presurgery chemotherapy, 22 to post-operative chemotherapy. Most common toxicities are neutropenia, thrombocytopenia, stomatitis/mucositis and elevated transaminases. Treatment specific response remains masked but overall disease-free survival curve and life table analysis has been provided.



### Detail Summary Sheet

Prot No: POG 8696/97(87)	Status: Ongoing
TITLE: Treatment of Hepatoblastoma (HB) with Surgery, Chemotherapy, and Radiation Therapy	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: hepatoblastoma (HB);	
Funding: FY 88: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** This is a study directed toward comprehensive care of the child with hepatoblastoma. There is only scattered data on therapy or survival in this relatively rare tumor of childhood. This study will involve single arm studies of each stage of the disease using the anticipated best available therapy for each stage. This study will establish a benchmark for future therapies and explore the importance of several factors including: 1) Histology 2) Modern studying and surgical therapy, 3) Alpha-fetoprotein levels, 4) chemotherapy (cis-platinum, vincristine, 5-FU for 80 days), and 5) Radiotherapy to localized unresectable disease.

**TECHNICAL APPROACH:** These are single armed studies stratified by stage. There is no randomization.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1    Reporting Period: 1

Nationally 59 fully evaluable patients are available. All patients with measurable disease have had at least a partial response to chemotherapy. 8696: Stage I, One patient has relapsed with AFP negative tumor. Three others remain free of disease post surgery. 8697: Stage IIA, 9 patients remain in remission after surgery (27-30 mo). Stage II C, 3 patients are in remission 27 to 30 months from surgery. One death from unrelated causes. Stage III, 10 of 12 patients achieved complete remission with surgery following chemotherapy. They remain disease free 3-30 months post surgery. Two patients achieved only partial remission and went on to liver transplant. One remains alive. Stage IV: 12 evaluable patients. Eight achieved complete remission with chemotherapy and surgery. Two of these children have relapsed. Four patients achieved only a partial remission and 3 of these have died.

Most patients have experienced grade IV hematologic toxicity. One patient had severe electrolyte problems requiring reduction of cis-platinum.

### Detail Summary Sheet

Prot No: POG 8704(89)	Status: Ongoing
TITLE: T-Cell #3 Protocol	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Pediatric Hematology/Oncology Section	
Key Words: lymphoblastic lymphoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** 1) To determine efficacy of multiagent chemotherapy targeted for patients with T-cell malignancies (leukemia and advanced T-cell lymphoblastic lymphoma). 2) To determine value of high dose L-asparaginase in the first phase of maintenance chemotherapy. 3) To study the biology of malignant T-cell disease.

**TECHNICAL APPROACH:** Common 14 week induction therapy of Vincristine, Prednisone, Cytosine, Adriamycin, VM-26, Ara-C, Asparaginase and CNS Prophylaxis or treatment followed by randomization to one of two treatment arms: Trt I - 10 nine-week cycles of alternating Cytosine/Ara-C, Vincristine/Pred/Adriamycin/6-MP, and VM-26/Ara-C Trt II along with L-asparaginase weekly x 20 weeks starting at beginning of maintenance.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One TAMC patient enrolled to date, subsequently transferred to another POG institution (WRAMC) for continued therapy on protocol.

POG April 1989 report reveals 182 patients registered as of Nov88. Post induction CR is 99% for T-ALL, 95% for T-NHL. Disease free survival at two years (8691/8704 combined) appears superior to LSA<sub>2</sub>L<sub>2</sub> + XRT.

Comparison between arms remains masked. Two year disease free survival figure is provided.

### Detail Summary Sheet

Prot No: POG 8725(88)	Status: Ongoing
TITLE: Randomized Study of Intensive Chemotherapy (MOPP/ABVD) + Low-Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, ITIA <sub>2</sub> , IIIB, IV Hodgkin's Disease in Pediatric Patients	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: total nodal radiation therapy (TNRT);	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** a. To determine, in a randomized study, whether the addition of Low-dose total nodal radiation therapy (TNRT) in pediatric patients with Hodgkin's disease who have achieved a complete remission after receiving 4 courses of MOPP alternating with 4 courses of ABVD will improve the duration of complete remission and survival when compared to patients who have received chemotherapy alone. b. To determine whether TNRT will significantly (i.e., grade 3 or 4) increase either acute toxicity or long-term morbidity when compared to MOPP/ABVD alone. c. To determine the effect of chemotherapy as compared to chemotherapy plus TNRT on splenic function as determined by the pitted erythrocyte count using Nomarski optics.

**TECHNICAL APPROACH:** Randomized treatment study (National protocol). Following chemotherapy of MOPP/ABVD, those patients assessed to be disease free will be equally randomized to TNRT or no further therapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

POG April 89 report indicates 38 patients enrolled through Nov 1988. Limited response data available. Too early for toxicity or survival assessment.

### Detail Summary Sheet

Prot No: POG 8741/42(87)	Status: Ongoing
TITLE: Treatment of Stage D Neuroblastoma in Children Greater Than or Equal to 365 Days at Diagnosis	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: neuroblastoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

OBJECTIVE: This study is designed to look specifically at children in the worst prognostic groups of neuroblastoma. This study will employ four phase two agents in addition to standard chemotherapy.

TECHNICAL APPROACH: Children will be randomized to receive one of 4 phase two agents as initial drug therapy. After two courses they will then be randomized to one of two standard treatment arms for completion of therapy. Results will be compared to historical group controls.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

POG April 89 report indicates 96 patients enrolled on POG 8741 and 87 on POG 8742 as of Nov 1988. Treatment specific induction response rates are marked but across all arms for the 86 evaluable patients PR is 37%, MR is 14%, No response is 34%. Most severe toxicity remains neutropenia and thrombocytopenia. The POG 8742 survival curve and life table for all patients is provided.

### Detail Summary Sheet

Prot No: POG 8764(88)

Status: Ongoing

TITLE: Chemotherapy Regimen for Early and Initial Induction Failures in Childhood Acute Lymphoblastic Leukemia - A Pediatric Oncology Group Phase II Study

Principal Investigator: LTC Bruce A. Cook, MC

Associate Investigators:

Department/Section: Pediatrics/Hematology-Oncology Service

Key Words: Lymphoblastic Leukemia

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** To estimate the complete remission rate for early and initial induction failures in childhood ALL based on an induction regimen of VM-26 and continuous infusion cytosine arabinoside (Ara-C); to estimate the one-year disease-free survival for early and initial induction failures in childhood ALL, based on a new regimen; to try and better characterize this unique subpopulation of patients with primary drug resistance using cDNA probes for the multidrug-resistant phenotype and obtain an oncogene profile.

**TECHNICAL APPROACH:** Remission induction with standard dose continuous ARA-C, high dose VM-26 and TIT. Continuation therapy with MTX, ARA-C, VM-26, Daunomycin and 6-MP.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

POG April 89 report reveals slower than expected patient accrual with only 7 patients enrolled to date (6 patients/years vs projected 9/yr). Data available on 6 patients reveal 1 CR, 3 PR, 2 nonresponders.

Detail Summary Sheet

Prot No: POG 8821(88)	Status: Ongoing
TITLE: AML#3: Intensive Multiagent Therapy vs. Autologous Bone Marrow Transplant Early in First CR for Children with Acute Myelocytic Leukemia	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology Service	
Key Words: acute myelocytic leukemia;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Continue
Gifts: None	

OBJECTIVE: a) To determine the disease-free survival (DFS) and event-free survival (EFS) in childhood acute myelocytic Leukemia (AML) offered by intensive chemotherapy with alternating non-cross resistant drug combinations for nine courses. b) To determine if short (three course) intensive chemotherapy (identical to the first three courses of the above regimen) followed by autologous bone marrow transplant (BMT) using the Busulfan/Cytosan preparative regimen and 4-Hydroperoxycyclophosphamide (4-HC) purged marrow is effective therapy. c) To compare, in a randomized study, the results of the above two regimens. d) To correlate the treatment outcome with clinical and laboratory features.

TECHNICAL APPROACH: Patients to be equally randomized (after remission induction with 6-TG, ARA-C and Daunomycin to standard chemotherapy for maintenance or autologous bone marrow with 4-HC purging and no further therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

POG April 1989 report reveals 59 patients enrolled through Dec 1988. CR achieved in 39 of 46 (84.8%) patients with data sufficient for evaluation.

### Detail Summary Sheet

Prot No: POG 8850(89)	Status: Ongoing
TITLE: Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly-Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone: A Phase III Intergroup Study	
Principal Investigator: LTC Bruce A. Cook, MC	
Associate Investigators:	
Department/Section: Pediatrics/Pediatric Hematology/Oncology Section	
Key Words: Ewing's sarcoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** Primarily: To determine and compare the EFS of patients treated with VP-16 and Ifosfamide in addition to standard therapy vs treatment with standard therapy alone. Secondarily: a) Evaluate toxicities and adverse orthopedic outcomes associated with disease and therapies; b) Assess significance of tumor site, size, histology and EM pattern in determining outcome; c) Correlate imaging characteristics with response, prognosis, RT adequacy, and survival; d) Assess prognostic value of cellular DNA content and chromosome changes.

**TECHNICAL APPROACH:** Patients with newly diagnosed Ewing's sarcoma or PNET of bone will be evenly randomized to one of two treatment arms: Reg A-52 week course of chemo including Vincristine, Adriamycin, Cytosan, Actinomycin D with surgery and/or XRT as needed (standard therapy). Reg B-52 week including Ifosfamide and Etoposide as well as therapy employed in Regimen A.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

POG April 1989 report reveals 12 patients accrued. No results reported to date.

Detail Summary Sheet

Prot No: SWOG 7804(84)	Status: Ongoing
TITLE: Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin C (FAM) versus Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; COL Peter J. Barcia, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: gastric adenocarcinoma	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Continue

OBJECTIVE: To determine whether or not chemotherapy (FAM) given to patients with advanced but resected gastric carcinoma will prevent relapses and prolong life.

TECHNICAL APPROACH: Patients will be randomized to either (1) receive chemotherapy with FAM twice a month for 1 year or (2) receive no treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

National accrual continues and completion of this study will hopefully be in the near future. Toxicity has been mild.



### Detail Summary Sheet

Prot No: SWOG 8312(85)	Status: Ongoing
TITLE: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Metastatic Breast Cancer, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: breast cancer, metastatic	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine if combined hormone therapies are superior to single hormone therapy in sequence for metastatic breast cancer.

**TECHNICAL APPROACH:** All patients agreeing to this study will be randomized to one of three treatments: (1) megestrol acetate, (2) aminoglutethimide plus hydrocortisone, or (3) megestrol acetate plus aminoglutethimide plus hydrocortisone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There are no TAMC patients on this study. Study remains open with no unanticipated toxicity. Accrual is adequate.

Detail Summary Sheet

Prot No: SWOG 8324(87)	Status: Completed
TITLE: Evaluation of Fludarabine Phosphate in Malignant Melanoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC;	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: fludarabine phosphate; metastatic melanoma	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Completed

OBJECTIVE: To determine the response rate and response duration in patients with malignant melanoma treated with fludarabine phosphate.

TECHNICAL APPROACH: Patients agreeing to participate will receive fludarabine IV push daily for 5 days every 4 weeks until relapse.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study is completed. There were no partial or complete remissions. There also was no serious toxicity.

Detail Summary Sheet

Prot No: SWOG 8326/27(85)

Status: Ongoing

TITLE: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blast Crisis, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: LTC William J. Uphouse, MC; MAJ Luke M. Stapleton, MC; MAJ Lawrence Sakas, MC

Department/Section: Medicine/Hematology-Oncology Service

Key Words: leukemia, adult acute; leukemia, chronic granulocytic

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** To determine the response and response duration of a high-dose program of Ara-C in patients with relapsed acute leukemia.

**TECHNICAL APPROACH:** Patients agreeing to the study will be randomized to receive (1) six days of high dose Ara-C, (2) the same Ara-C plus three days of m-AMSA, or (3) the same Ara-C plus three days of Mitoxantrone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

Accrual has been slow nationally to date but continues. High dose Ara-C continues to be the most promising drug in relapsed leukemia. The one TAMC patient registered on this study achieved a complete remission of her leukemia and did well for 9 months but then relapsed and died. Nationally the arm of the study with m-AMSA had 9 deaths among 39 patients so it is being terminated. Toxicity in the other 2 arms has been very tolerable.

### Detail Summary Sheet

Prot No: SWOG 8393(84)	Status: Ongoing
TITLE: National Intergroup Protocol for Intermediate Thickness Melanoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; COL Peter J. Barcia, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: melanoma	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: (1) To determine the optimal surgical margins (2 versus 4 cm) around the intermediate thickness melanomas (1-4 mm) that are being resected for cure. (2) To evaluate the value of elective regional lymph node dissection in these same melanomas.

TECHNICAL APPROACH: Patients with primary melanomas of the head or neck or distal extremities will be randomized to receive or not receive elective node dissection, but all patients in this group will have 2 cm surgical margins. Patients with melanomas of the trunk or proximal extremities will undergo two randomizations, (1) to receive or not to receive elective node dissection, and (2) to have either a 2 or 4 cm surgical margin.

PROGRESS: No. of Subjects Enrolled - To Date: 2      Reporting Period: 0

Two Tripler patients have been registered on this protocol. It is too early to assess efficacy of this protocol approach.

### Detail Summary Sheet

Prot No: SWOG 8417/19(85)	Status: Ongoing
TITLE: Evaluation of the Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; MAJ Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Leukemia, Lymphoblastic	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare two consolidation chemotherapy programs in terms of remission, duration, and survival.

**TECHNICAL APPROACH:** All patients agreeing to participate will be randomized to receive either the L-10M consolidation or the new (shorter) consolidation program.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 3

This study is the frontline study for patients with newly diagnosed acute lymphoblastic lymphoma and remains open. Of the 4 TAMC patients entered on this study, all 4 entered complete remission but one has relapsed. Nationally there is no data yet available except for a few deaths which are expected in treating acute leukemia.

Detail Summary Sheet

Prot No: SWOG 8507(86)

Status: Completed

TITLE: Maintenance vs No Maintenance BCG Immunotherapy of Superficial Bladder Cancer, Phase III

Principal Investigator: COL Martin L. Dresner, MC  
(formerly: COL Douglas Soderdahl, MC)

Associate Investigators: LTC W. Kennon, MC; MAJ F. Sateri, MC;  
CPT Karl Kreder, MC; CPT M. Pliskin, MC;  
LTC Lawrence Sakas, MC

Department/Section: Surgery/Urology Svc

Key Words: bladder cancer

Funding: FY 88: NA FY 89: NA

Periodic Review Date: Sep 89

Gifts: BCG NSC B116341

Decision: Complete

OBJECTIVE: To compare effectiveness of maintenance vs no maintenance BCG and to assess relative toxicities of these two approaches and to assess the association of intermediate strength PPD skin test reactivity with disease-free status in patients so treated.

TECHNICAL APPROACH: Patients who meet criteria and who consent to participate will be registered for induction treatment, then randomized at a second registration. BCG Connaughtis is diluted in 50.5 cc sterile saline and 50 cc is placed intravesically for two hours, 0.5 cc is administered subcutaneously to the upper thigh. Maintenance patients receive similar therapy weekly every six weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 7 Reporting Period: 2

Study completed by departed investigator. Data being collected at SWOG.

### Detail Summary Sheet

Prot No: SWOG 8509(86)	Status: Completed
TITLE: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: prostate adenocarcinoma	
Funding: FY 88: NA	FY 89: NA
Gifts: Menogaril	Periodic Review Date: Mar 89
	Decision: Completed

OBJECTIVE: To determine the response rate of metastatic prostate cancer to a new Adriamycin-like drug, Menogaril, in patients who have failed hormone therapy.

TECHNICAL APPROACH: Patients agreeing to the study will receive the drug once every 28 days IV over one hour.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

One TAMC patient was entered on this study. Only 4 patients out of 79 patients entered nationally had a partial remission. Nationally there were 2 treatment-related deaths due to leukopenia, but toxicity was otherwise mild.

### Detail Summary Sheet

Prot No: SWOG 8514(86)	Status: Terminated
TITLE: Randomized Comparison of Cisplatin + 5-Fluorouracil vs. CBDCA + 5-Fluorouracil vs. Methotrexate in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: carcinoma, squamous cell	
Funding: FY 88: NA	FY 89: NA
Gifts: CBDCA	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To compare the response rate of two relatively new chemotherapy combinations (5-FU + Cisplatin vs. CBDCA + 5-FU) with standard therapy, i.e., methotrexate, in advanced head and neck cancer.

**TECHNICAL APPROACH:** Patients agreeing to the study will be randomized to receive one of three regimens: (1) methotrexate IV weekly, (2) Cisplatin + 5-FU IV every 4 weeks, or (3) CBDCA + 5-FU IV every 4 weeks.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

Two patients were entered from TAMC. One patient did well on the carboplatin arm for 1 year but relapsed and eventually died. The 2nd one received cisplatin and 5FU and also responded (partial remission) but he, too, relapsed. Nationally the study just terminated after adequate patient accrual but there are no results yet. Toxicity has been relatively mild.



### Detail Summary Sheet

Prot No: SWOG 8516(86)	Status: Ongoing
TITLE: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBOM vs MACOP-B in Patients with Intermediate and High-Grade Non-Hodgkin's Lymphoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: lymphoma, non-Hodgkin's	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine which of the four leading chemotherapy programs for aggressive lymphomas is best in terms of response, survival, and toxicity.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will be randomized to receive one of the four treatment programs listed above.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 1

We have been slow to accrue non-Hodgkin's cases because these cases have been relatively uncommon hospital-wide this year. Of the 2 patients entered on this study both went into complete remission but 1 has relapsed. Nationally there are no data yet.

### Detail Summary Sheet

Prot No: SWOG 8530(86)	Status: Ongoing
TITLE: Efficacy of Prednisone in Refractory and Relapsing Multiple Myeloma and Measurement of Glucocorticoid Receptors, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC, MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: myeloma; glucocorticoid receptors	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To estimate the response rate and duration of response with high dose prednisone in patients with refractory myeloma.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive 100 mg of prednisone every other day for two weeks, then 50 mg every other day for ten weeks.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

This protocol was approved in September 1986. The one patient entered at Tripler has had an excellent response to this therapy, and remains in an excellent partial remission for almost 2 years. Nationally, other patients have responded well to this therapy but exact statistics have not been released. Toxicity has been very mild.

Detail Summary Sheet

Prot No: SWOG 8590(85) (previously 8591)	Status: Ongoing
TITLE: Phase III Study to Determine the Effect of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC;	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: carcinoma, squamous cell	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine if adding chemotherapy will improve results of surgery and radiation for advanced (Stage III and IV) but resectable head and neck cancer.

TECHNICAL APPROACH: All patients agreeing to participate in the study will be randomized to receive (1) surgery, then radiation therapy, or (2) surgery, then three cycles of chemotherapy (cisplatinum plus 5-FU), then radiation.

PROGRESS: No. of Subjects Enrolled - To Date: 3      Reporting Period: 3

Of the 3 patients entered on this study to date, one received chemotherapy and is doing well. A second patient didn't receive treatment and relapsed, and a third patient left the island unexpectedly and has been lost to followup.

Detail Summary Sheet

Prot No: SWOG 8594(86)	Status: Terminated
TITLE: A Phase III Trial of Cis-platinum Alone or in Combination with Doxorubicin, Vinblastine and Methotrexate in Advanced Bladder Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: cancer, bladder	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89
	Decision: Terminate

OBJECTIVE: To determine if cis-platinum in combination with doxorubicin, vinblastine, and methotrexate is more effective than cis-platinum alone in the treatment of patients with advanced bladder cancer in terms of objective response rate, response duration, and survival.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive either (1) cis-platinum IV every 28 days until disease progression or (2) cis-platinum, doxorubicin, vinblastine, and methotrexate IV every four weeks until disease progression.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study was just terminated recently as it achieved it's targeted number of patients. Of 180 patients 1 died of toxicity and 21 had life-threatening toxicity. No results are available yet.

### Detail Summary Sheet

Prot No: SWOG 8598 (87)

Status: Ongoing

TITLE: A Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation and Chemotherapy, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: LTC William J. Uphouse, MC; MAJ Luke M. Stapleton, MC;  
CPT Scott Martin, MS; LTC Lawrence Sakas, MC;

Department/Section: Medicine/Hematology-Oncology Service

Key Words: esophagus, cancer, radiation, chemotherapy

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: None

Decision: Continue

**OBJECTIVE:** To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus. Specifically, to determine if the combination of chemotherapy and radiation will add to the overall survival and cure of patients treated with the combination when compared to patients treated by radiation alone.

**TECHNICAL APPROACH:** Patients agreeing to the study will be randomized to receive (1) radiation alone (6400 rads in 6½ weeks) or (2) radiation (5,000 rads in 5 weeks) beginning simultaneously with four cycles of chemotherapy (cisplatin plus 5-FU).

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

One patient from Tripler entered. He was randomized to radiation alone, has completed treatment, but died about 8 months later due to recurrent disease. Nationally, no results are available, except that there have been no life-threatening toxicities among the 65 patients entered to date.

Detail Summary Sheet

Prot No: SWOG 8600(87)	Status: Ongoing
TITLE: A Randomized Investigation of High Dose Versus Standard Dose Cytosine Arabinoside With Daunorubicin In Patients With Acute Non-Lymphocytic Leukemia	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC;	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: cytosine arabinoside and daunorubicin	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare, among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose cytosine arabinoside and daunorubicin or high dose cytosine arabinoside and daunorubicin. Also to compare these 2 programs when used in the consolidation phase.

**TECHNICAL APPROACH:** Patients are randomized to receive standard or high dose cytosine arabinoside initially. If remission is achieved then patients are randomized again to receive standard or high dose cytosine arabinoside for consolidation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 2

Of the 3 TAMC patients enrolled on this study in 1988-89, 2 achieved a complete remission but one relapsed after 1 year. Nationally there are no data yet on response but of 305 patients evaluable for induction toxicity, 11 died as a result of therapy. Due to the toxic nature of leukemia treatment in general, this figure is probably not high.

### Detail Summary Sheet

Prot No: SWOG 8605 (86)	Status: Terminated
TITLE: Cyclophosphamide, Ara-C Infusion and Vincristine for Relapsed or Refractory Extensive Small Cell Lung Cancer, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; MAJ L. M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC; MAJ Marianne M. Young, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: lung cancer; small cell	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To determine the efficacy of a new chemotherapy combination in relapsing or refractory small cell lung cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive cytoxan and Ara-C every 3 weeks for four cycles, then prophylactic cranial irradiation, then two more cycles of the chemotherapy. Vincristine will also be given with the other two drugs.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 0

The study was recently terminated. One of the two TAMC patients achieved a near complete remission of his relapsed extensive small cell lung cancer and did well for 9 months but then relapsed and died. Nationally, there were only 4% partial responses. However, toxicity was fairly mild. 65 patients total were assessed nationally.

### Detail Summary Sheet

Prot No: SWOG 8611(87)	Status: Terminated
TITLE: A Randomized Trial of Two Schedules of Trimetrexate versus 5-Fluorouracil in Colorectal Carcinoma, Phase II-III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Trimetrexate vs. 5-Fluorouracil in Colorectal Carcinoma	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To determine and compare the response rates, response durations and toxicities of trimetrexate given on two different schedules to patients with advanced colorectal cancer. Also to compare patient survival on trimetrexate versus that on 5FU.

**TECHNICAL APPROACH:** Patient agreeing to participate in the study are randomized to receive trimetrexate by either of 2 IV schedules on to receive 5FU IV.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

The one TAMC patient entered was randomized to receive trimetrexate and has had stable disease with this on follow-up CT scans but after 6 months had progressive disease and died. Nationally, there are no data on response but toxicity was reported to be very mild. The study was terminated as it reached its targeted patient accrual.



### Detail Summary Sheet

Prot No: SWOG 8616(87)	Status: Ongoing
TITLE: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine With or Without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: ifosfamide, mesna	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine if adding ifosfamide and mesna to the usually employed drugs of doxorubicin and dacarbazine will improve the response rate, response duration and survival in metastatic soft tissue and bone sarcoma.

**TECHNICAL APPROACH:** Patients agreeing to participate will have a central line (port-a-cath) placed and receive 4 days of doxorubicin and dacarbazine continuously through this line. These patients will also be randomized to receive or not receive 4 days of therapy with ifosfamide and mesna. These latter drugs are given together through a peripheral IV (in patients randomized to receive them). This whole chemotherapy regimen is repeated every 3 weeks until disease progression is noted.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

The one TAMC patient entered had stabilization of his disease with the 4 drug arm for 8 months but now shows signs of progression. Clinically, he is doing well, though. Nationally there were 6 deaths among 116 evaluated patients on the 4 drug arm so the ifosfamide dose is reduced. No data are available on response, but long term survivors have been reported in other studies.

### Detail Summary Sheet

Prot No: SWOG 8617(87)	Status: Completed
TITLE: Evaluation of Interleukin 2 in Metastatic Renal Cell Carcinoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Metastatic Renal Cell Carcinoma	
Funding: FY 88: NA	FY 89: NA
Gifts: Interleukin 2	Periodic Review Date: Sep 89 Decision: Completed

**OBJECTIVE:** To determine the response rate and the remission duration in metastatic renal cell carcinoma treated with Interleukin 2.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will receive Interleukin 2 by IV bolus three times a week until disease progression is noted.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 0

Of the 2 TAMC patients entered on the study, one had no toxicity from the drug but also had no response to it. A second patient had dramatic reduction in pulmonary metastases but experienced flu-like symptoms (as expected). Her tumor progressed after 4 months, and she died. Nationally 10% of patients had partial remissions and no serious toxicity was reported.

### Detail Summary Sheet

Prot No: SWOG 8624(87)	Status: Ongoing
TITLE: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma (1) Comparison of VMCP/VBAP to VAD or VMCP/VBAPP for Induction; (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha-2b Interferon + Dexamethasone for Incomplete or Non-Responders	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC;	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: multiple myeloma; Alpha-2b Interferon	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** (1) To compare SWOG's best induction chemotherapy program for myeloma with two other very promising programs; (2) to determine if interferon is a better maintenance program than no treatment; and (3) to determine if interferon plus decadron can salvage patients who do not respond satisfactorily to the above induction programs.

**TECHNICAL APPROACH:** Patients agreeing to the study will be randomized to receive one of the three induction programs. Those who achieve a response (75% M-protein reduction) will be randomized to receive or not receive interferon. Those not achieving response will be offered the above salvage program.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

Two TAMC patients have been entered on this study and one is responding well to therapy (at least a partial remission). The other patient did not respond and is on other treatment. Nationally there are no response data yet. As expected, toxicity has been very mild.

Detail Summary Sheet

Prot No: SWOG 8632(87)	Status: Terminated
TITLE: Evaluation of Echinomycin in Central Nervous Systems Tumors, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC;	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Echinomycin	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	
Gifts: Echinomycin	Decision: Terminate

OBJECTIVE: To assess the efficacy of echinomycin in recurrent or residual central nervous system tumors by evaluation of response rate, response duration, and survival.

TECHNICAL APPROACH: Patients agreeing to participate in the study will receive courses of treatment (once a week IV for 4 weeks then 2 weeks rest) until disease progression is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This has accrued its targeted patient numbers and has been terminated. No response information is available yet. There was no serious toxicity.

### Detail Summary Sheet

Prot No: SWOG 8642(87)

Status: Ongoing

TITLE: Recombinant Human Interferon-Gamma for the Adjuvant Treatment of High Risk Malignant Melanoma after Surgical Excision of the Primary Lesion, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS

Department/Section: Medicine/Hematology-Oncology Service

Key Words: Recombinant Human Interferon-Gamma

Funding: FY 88: NA

FY 89: NA

Periodic Review Date: Sep 89

Gifts: Recombinant Human Interferon-Gamma

Decision: Continue

**OBJECTIVE:** To compare the survival and disease-free survival among patients who are at high risk for recurrence of melanoma following resection of all known disease, and who are randomized to receive recombinant human interferon-gamma adjuvant therapy or no adjuvant therapy.

**TECHNICAL APPROACH:** Patients agreeing to participate in the study will be randomized to receive or not receive interferon-gamma subcutaneously once a day for 12 months.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study is still accruing patients nationally. No serious toxicity has been noted in the 158 patients registered to date.

### Detail Summary Sheet

Prot No: SWOG 8691(89)	Status: Ongoing
TITLE: A Randomized Comparison of Deoxycoformycin vs. Alpha Interferon in Previously Untreated Patients with Hairy Cell Leukemia	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: deoxycoformycin; alpha interferon	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To compare the rates of partial and complete remission and the durations of survival in patients treated with the alpha interferon or deoxycoformycin.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive 1) alpha interferon subcutaneously three times a week for 6 months and then be reassessed for a second 6 months of treatment or 2) deoxycoformycin IV every 2 weeks until the leukemia is gone.

PROGRESS: Nu. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Nationally, there are no response data available (although we know from other studies the responses will be very high). Among the 231 patients registered to date there were a number (about 30 in each arm) of cases of very low white blood cell counts but not associated with fever.

### Detail Summary Sheet

Prot No: SWOG 8703(88)	Status: Terminated
TITLE: Evaluation of Vinblastine and High-Dose Cis-platinum in the Treatment of Advanced Non-small Cell Lung Carcinoma, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS;	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: vinblastine;	
Funding: FY 80: NA    FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Terminate

**OBJECTIVE:** To determine the activity of a new program of combination chemotherapy in the treatment of advanced non-small cell lung cancer.

**TECHNICAL APPROACH:** Patient agreeing to participate will receive Cis-platinum 100 mg/M<sup>2</sup> and Vinblastine on day 1 and 8 each month for 3 months and then no further treatment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 0

This study has opened recently and one of the two TAMC patients has had a 80% tumor reduction with this program. His tumor filled almost his entire left lung initially. The second patient had no response. The first patient did well for about 11 months and then relapsed and died. Nationally the study has been terminated as it has reached its patient accrual goal. There are no results yet except that there was no serious toxicity.

Detail Summary Sheet

Prot No: SWOG 8710(89)	Status: Ongoing
TITLE: Trial of Cystectomy Alone Versus Neoadjuvant M-VAC plus Cystectomy in Patients with Locally Advanced Bladder Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; COL Martin Dresner, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Medical/Hematology-Oncology Service	
Key Words: cystectomy;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To compare the survival of patients with locally advanced bladder cancer treated with either cystectomy alone or cystectomy plus chemotherapy with M-VAC (Methotrexate, Vinblastine, Adriamycin and Cisplatin).

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive 1) cystectomy alone or 2) 3 cycles of M-VAC chemotherapy and then cystectomy.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

The one TAMC patient enrolled was randomized to the chemotherapy arm and had a good response to chemotherapy. He has had his surgery and is doing well on a recent followup visit. Nationally the only data available are the lack of any serious toxicity in the patients treated to date.



Detail Summary Sheet

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Prot No: SWOG 8711(89) Status: Ongoing

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TITLE: A Study of Reproductive Function in Patients with Testicular Cancer

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Principal Investigator: COL Jeffrey L. Berenberg, MC  
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC;  
MAJ Luke M. Stapleton, MC; COL Martin L. Dresner, MC;  
MAJ Marianne Young, MC

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Department/Section: Medicine/Hematology-Oncology Service

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Key Words: testicular cancer;

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Funding: FY 88: NA FY 89: NA Periodic Review Date: Sep 89  
Gifts: None Decision: Continue

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OBJECTIVE: To evaluate the natural history of seminal fluid and hormone parameters in patients with testicular cancer after orchiectomy and after other treatments such as retroperitoneal node dissection, chemotherapy, and radiation therapy.

TECHNICAL APPROACH: Patients agreeing to participate will have semen analysis beginning after orchiectomy and these will occur every 3 months for 3 years then every 6 months out to 5 years. Testosterone and FSH blood levels will also be done but only half as often as the semen analysis.

PROGRESS: No. of Subjects Enrolled - To Date: 2 Reporting Period: 2

There are no data available yet on this natural history study.

### Detail Summary Sheet

Prot No: SWOG 8712(88)	Status: Completed
TITLE: A Phase II Trial of Trimetrexate in the Treatment of Hepatoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC, CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: trimetrexate; hepatoma	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Complete

**OBJECTIVE:** To determine the efficacy of Trimetrexate, a new drug, in unresectable hepatoma.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive Trimetrexate daily for 5 days IV every 3 weeks until disease progresses.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

This study has been completed nationally as it has reached its patient accrual goal. There were no responses seen.

Detail Summary Sheet

Prot No: SWOG 8722(89)	Status: Terminated
TITLE: Evaluation of Amonafide in Adenocarcinoma of th. Prostate, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: amonafide; adenocarcinoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To determine the response rate and response duration of hormonally refractory adenocarcinoma of the prostate to Amonafide.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive Amonafide IV over 1 hour Day 1-5 every 21 days until tumor progression is documented.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One TAMC patient entered on this study had no response to treatment but also had little toxicity. Nationally the study has been terminated as it has accrued its target number of patients. No data are available yet.

Detail Summary Sheet

Prot No: SWOG 8736(88)	Status: Ongoing
TITLE: Treatment of Localized Non-Hodgkin's Lymphoma: Comparison of Chemotherapy (CHOP) to Chemotherapy Plus Radiation Therapy	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Non-Hodgkin's Lymphoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To compare the survival rates and toxicity of two curative approaches in patients with localized (stage I & II), intermediate or high grade non-Hodgkin's lymphoma.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive either 1) 8 cycles of chemotherapy (CHOP) or 2) 3 cycles of CHOP and then 4000 rads of radiation to the involved area.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently after some administrative delays. There are no data available yet.

### Detail Summary Sheet

Prot No: SWOG 8738(88)	Status: Ongoing
TITLE: Treatment of Extensive Non-Small Cell Lung Cancer: Standard Dose Cisplatin vs High-Dose Cisplatin in Hypertonic Saline Alone vs High-Dose Cisplatin/Mitomycin-C	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: cisplatin;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare standard dose Cisplatin chemotherapy to high-dose Cisplatin alone and to high-dose Cisplatin plus Mitomycin-C in a randomized study with attention to response rate, response duration and survival in metastatic non-small cell lung cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to 1) 8 cycles of standard dose Cisplatin (50mg/M<sup>2</sup> Day 1 and 8) or 2) 4 cycles of high-dose Cisplatin (100mg/M<sup>2</sup> Day 1 and 8) or 3) 4 cycles of high-dose Cisplatin (as above) plus Mitomycin-C.

**PROGRESS:** No. of Subjects Enrolled - To Date: 3      Reporting Period: 3

Of the 3 TAMC patients treated to date 2 have had partial remissions and one had no response. Of 61 patients entered nationally there has been no serious toxicity, but no response data are available yet.

### Detail Summary Sheet

Prot No: SWOG 8788(88)	Status: Terminated
TITLE: Evaluation of "High-Dose" versus "Standard-Dose" cisplatin Combined with Bleomycin and VP-16 for Advanced Testicular Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: Bleomycin;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

OBJECTIVE: To compare the efficacy of the standard Cisplatin regimen for advanced (greater than 10 cm) testicular cancer with a new high dose Cisplatin regime.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive the standard regimen of Cisplatin, VP-16, and Bleomycin every 3 weeks x 4 cycles or to receive the same regimen except with a higher Cisplatin dose.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just been terminated but no results are available.

Detail Summary Sheet

Prot No: SWOG 8789(89)	Status: Ongoing
TITLE: A Randomized Study of Etoposide + Cisplatin and Etoposide + Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: etoposide; cisplatin; carboplatin (CBDCA);	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Continue
Gifts: None	

OBJECTIVE: To determine the differences in response rate, time to relapse and survival between two active chemotherapy regimens, VP-16 plus Cisplatin and VP-16 plus Carboplatin for good risk patients with germ cell tumors.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive either 1) VP-16 plus Cisplatin IV every 3 weeks for 4 cycles or 2) VP-16 plus Carboplatin IV every 4 weeks for 4 cycles.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently and there are no data available yet.

### Detail Summary Sheet

Prot No: SWOG 8791(89)	Status: Ongoing
TITLE: Adjuvant Trial of Soft Tissue Sarcoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; LTC Y-T Margaret Lee, MC; MAJ Luke M. Stapleton, MC; MAJ Marianne M. Young, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: adriamycin;ifosfamide;mesna	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** Patients who have a high grade (Grade III) soft tissue sarcoma completely removed surgically have about a 25% 5-year survival. this study seeks to improve this statistic.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive either 1) chemotherapy with Adriamycin, DTIC, Ifosfamide and Mesna given continuously IV over 4 days in the hospital every 3 weeks for 6 cycles or 2) no treatment.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently and there are no data available yet.



Detail Summary Sheet

Prot No: SWOG 8792(87)	Status: Ongoing
TITLE: Phase III Study of Alfa-n1 (Wellferon) as Adjuvant Treatment for Resectable Renal Cell Carcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: interferon alfa-n1;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine the effectiveness of interferon alfa-n1 in prolonging time to recurrence and patient survival after resection of renal cell carcinoma.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive Interferon alfa-n1 IM daily for 5 days every 3 weeks for 12 cycles (36 weeks total) or be randomized to observation alone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

The one TAMC patient entered on this trial had a lot of flu-like symptoms and elected to stop treatment after the first cycle. His symptoms were short-lived but unacceptable to him. Nationally there are no data yet.

### Detail Summary Sheet

Prot No: SWOG 8793(88)	Status: Ongoing
TITLE: Randomized Phase III Evaluation of Hormonal Therapy vs. Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: hormonal therapy; pelvic lymphadenectomy; radical prostatectomy	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare the time to progression and the survival time for patients with resected stage D1 (positive lymph nodes) prostate cancer when they receive immediate hormone therapy vs. hormone therapy when the disease progresses.

**TECHNICAL APPROACH:** Patients agreeing to participate in the study will be assigned to receive hormone therapy or observation. If they are assigned to the hormone therapy arm, the patient may choose either orchiectomy or zoladex (a hormone which given qmon SQ produces castrate testosterone levels and has no serious side effects).

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just opened recently. No data are available yet.

### Detail Summary Sheet

Prot No: SWOG 8794(89)	Status: Ongoing
TITLE: Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; COL Martin L. Dresner, MC; MAJ Luke M. Stapleton, MS; MAJ Marianne M. Young, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: prostate carcinoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare in a randomized study the disease-free survival and overall survival of patients with completely resected Stage C prostate carcinoma (tumor through capsule or into seminal vesicles) given or not given adjuvant radiation therapy.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will be assigned to receive or not receive 6400 rads of radiation to the prostate bed.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently and there are no data available yet.

### Detail Summary Sheet

Prot No: SWOG 8795(89)	Status: Ongoing
TITLE: Randomized Prospective Comparison of Bacillus Calmette-Guerin (BCG) and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder with DNA Flow Cytometric Analysis, Phase III	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; COL Martin L. Dresner, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: bacillus calmette-guerin (BCG); mitomycin-C;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Continue
Gifts: None	

OBJECTIVE: To compare the efficacy of Bacillus Calmette-Guerin (BCG) in preventing recurrence of superficial transitional cell carcinoma of the bladder with that of mitomycin-C.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive BCG intravesically weekly for 6 weeks then, beginning on week 8, monthly for 11 more treatments, or to receive mitomycin-C intravesically on the same schedule.

PROGRESS: Nu. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently and there are no data available yet.

### Detail Summary Sheet

Prot No: SWOG 8796(88)	Status: Terminated
TITLE: Combination Chemotherapy for Advanced Hodgkin's Disease, Phase III Intergroup	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: Hodgkin's Disease	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Terminate

**OBJECTIVE:** To compare the efficacy of the two leading chemotherapy programs for advanced Hodgkin's disease.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to either the sequential MOPP-ABVD or hybrid MOPP/ABV program.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 4

Of the 4 TAMC patients on this study, 2 have achieved a complete remission and the other 2 have a partial remission but are still on therapy and a complete remission is expected. Nationally, there are no data yet but toxicity has been mild.

Detail Summary Sheet

Prot No: SWOG 8804(88)	Status: Ongoing
TITLE: Evaluation of Cis-platinum and DTIC in Inoperable Stage III and Stage IV Melanoma	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: cis-platinum; DTIC; advanced melanoma;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine the response rate and efficacy of DTIC plus Cis-platinum in inoperable advanced melanoma.

TECHNICAL APPROACH: Patients agreeing to participate will receive DTIC and Cis-platinum IV day 1 every 3 weeks until progressive disease is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There are no data available yet on this study at the national level.

### Detail Summary Sheet

Prot No: SWOG 8805(88)	Status: Ongoing
TITLE: Neoadjuvant Cisplatin and VP-16 Plus Concurrent Chest and Brain Irradiation for Patients with Stage III Non-Small Cell Lung Carcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; MAJ Marianne M. Young, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: Cisplatin; VP-16;	
Funding: FY 88: NA      FY 89: NA	Periodic Review Date: Sep 89
Gifts: None	Decision: Continue

**OBJECTIVE:** To assess the response rate, resectability rate and, ultimately, survival in patients with locally advanced non-small cell lung cancer treated with simultaneous chemotherapy and radiation prior to assessment for possible surgery. The benefit of prophylactic cranial radiation will also be examined.

**TECHNICAL APPROACH:** Patients agreeing to participate will all receive 2 cycles of Cisplatin and VP-16 plus simultaneous chest and cranial radiation therapy. If they are then considered resectable, they will then have a thoracotomy with resection.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

The one TAMC patient entered on this study so far has done extremely well with all of his tumor (except one microscopic focus) disappearing after chemotherapy and radiation. He is doing well off all treatment. Nationally, there are no data available yet.

### Detail Summary Sheet

Prot No: SWOG 8809(89)	Status: Ongoing
TITLE: A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; MAJ Marianne M. Young, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: ProMACE-MOPP;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine the response rate and survival of low grade lymphoma patients treated with ProMACE-MOPP. Also to compare the disease-free survival in these patients who receive alpha interferon after chemotherapy compared to those who receive only the chemotherapy.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive 6 cycles of ProMACE-MOPP (followed by limited field radiation if complete remission is not achieved with the ProMACE-MOPP) and then be randomized to receive or not receive low dose alpha interferon 3 times a week subcutaneously for 2 years.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently and there are no data available yet.



### Detail Summary Sheet

Prot No: SWOG 8810(88)	Status: Ongoing
TITLE: Six Courses of 5-FU and Cis-platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinomas of the Head and Neck, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: squamous cell carcinomas;	
Funding: FY 88: NA	FY 89: NA
Periodic Review Date: Sep 89	Decision: Continue
Gifts: None	

OBJECTIVE: To determine if 6 cycles of Cis-platinum plus 5-FU will result in more complete remissions of locally advanced head and neck cancer than 3 cycles.

TECHNICAL APPROACH: Patients agreeing to participate will all receive 3 cycles of Cis-platinum plus 5-FU. Patient who then achieve at least a partial remission (50% or more tumor shrinkage) will get 3 additional cycles. With less than partial, come off study.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just opened. There are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8812(89)	Status: Ongoing
TITLE: SWOG 8812(89): Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent Randomization to Maintenance Interferon or No Maintenance	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LCT William J. Uphouse, MC MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC; MAJ Marianne M. Young, MC	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: GM-CSF	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine if alpha interferon given after induction chemotherapy and radiation prolongs survival in patients with limited small cell lung cancer. Also this study seeks to determine if GM-CSF will ameliorate the myelosuppression that occurs during induction therapy.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to either receive or not receive maintenance interferon 3 times a week SQ for 2 years after 6 cycles of chemotherapy with radiation with or without GM-CSF.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently and there are no data available yet.

### Detail Summary Sheet

Prot No: SWOG 8892(89)	Status: Ongoing
TITLE: A Study of Radiotherapy with and without Concurrent Cisplatin in Patients with Nasopharyngeal Cancer, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: nasopharyngeal cancer;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To compare the complete response rate and survival of patients with Stage III of IV Nasopharyngeal cancer treated with definitive radiation versus those treated with definitive radiation plus Cisplatin.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to receive either 1) radiation (7,000 rads over 7 weeks) or 2) the same radiation plus 3 doses of concurrent Cisplatin (at 3 week intervals).

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study opened recently and there are no data available yet.

Detail Summary Sheet

Prot No: SWOG 8899(88)	Status: Ongoing
TITLE: A Prospectively Randomized Trial of Low-Dose Leucovorin Plus 5-FU, High-Dose Leucovorin Plus 5-FU, or Observation Following Curative Resection in Selected Patients with Duke's B2 or C Colon Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; LTC Lawrence Sakas, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: leucovorin;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine if surgery plus either 5-FU and low dose Leucovorin or 5-FU and high dose Leucovorin will result in improved survival over surgery alone in resected Dukes's B2 and C colon cancer.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized post-operatively to receive 1) 5-FU plus low dose Leucovorin IV push Day 1-5 q4-5 weeks x 6 cycles, or 2) 5-FU plus high dose Leucovorin IV over 2 hours weekly for 6 of each 8 weeks for 24 doses, or 3) no chemotherapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

The one TAMC entered on this study was randomized to no chemotherapy and is presently doing well. Nationally, there are no data available yet as the study just opened.

Detail Summary Sheet

Prot No: SWOG 8900(89)	Status: Ongoing
TITLE: Randomization Trial fo VAD and VAD/Verapamil for Refractory Multiple Myeloma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC; MAJ Luke M. Stapleton, MC; CPT Scott Martin, MS. LTC Lawrence Sakas, MC	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: vincristine, adriamycin, dexamethasone, verapamil;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determien the response rate adn response duration to chemotherapy flone (VAD) and to chemotherapy (VAD) plus Verapamil in multiple myeloma patients who have failed previous chemotherapy.

TECHNICAL APPROACH: Patients agreeing to participate will be randomized to receive VAD given as a 4 day IV infusion or to receive the same VAD plus p.o. Verapamil.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study just opened and there are no data available yet.

### Detail Summary Sheet

Prot No: CRCH 8901(89)	Status: Ongoing
TITLE: Cancer Research Consortium of Hawaii - Phase II Evaluation of Hepatic Chemoembolization with Angiostat Collagen and Cisplatin, Mitomycin and Doxorubicin	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: hepatic chemoembolization; doxorubicin;	
Funding: FY 88: NA	FY 89: NA
Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

**OBJECTIVE:** To determine the efficacy of chemoembolization in unresectable metastatic tumors to the liver and primary hepatoma.

**TECHNICAL APPROACH:** Patients agreeing to participate will undergo hepatic artery catheterization for chemoembolization of the part of the liver. A second and subsequent chemoembolization will be done at intervals of 2 to 4 weeks to treat the rest of the liver.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study just opened and there are no available data yet.

### Detail Summary Sheet

Prot No: CRCH 8903(89)	Status: Ongoing
TITLE: A Multicenter Phase II Trial of Intravenous PEG-Interleukin-2 (Modified Recombinant Human) (PEG IL-2) in Patients with Advanced Renal Cell Carcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC Associate Investigators: LTC William J. Uphouse, MC	
Department/Section: Medicine/Medical Hematology-Oncology Service	
Key Words: Interleukin-2;	
Funding: FY 88: NA Gifts: None	Periodic Review Date: Sep 89 Decision: Continue

OBJECTIVE: To determine the response rate to PEG IL-2 in patients with advanced renal cell carcinoma.

TECHNICAL APPROACH: Patient agreeing to participate will receive PEG IL-2 over 15 minutes IV weekly for 8 weeks and then be reassessed for further treatment depending on their response. The patients will be hospitalized for 24 hours after the first dose to monitor for toxicity.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study just opened and there are no available data yet.

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